UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GLENN ALTO, EDWARD CONNOLLY in his individual capacity and as trustee of the Connolly 2014 Grantor Retained Annuity Trust, and LEWIS WILLIAM WATERS in his individual capacity and as trustee of the Lewis William Waters III 2014 Qualified Annuity Trust Plaintiffs, -v- SUN PHARMACEUTICAL INDUSTRIES, INC., Defendant.	1:19-cv-09758-GHW MEMORANDUM OPINION AND ORDER

GREGORY H. WOODS, United States District Judge:

In 2007, Plaintiffs Glen Alto, Edward Connolly, and Lewis William Waters completed a management buyout of a small radiopharmaceutical company. That company, which Plaintiffs renamed Pharmalucence, experienced growth and financial success through its development of generic radiopharmaceutical products and several contract manufacturing projects. In 2013, Plaintiffs engaged an investment bank to sell Pharmalucence, resulting in an acquisition by Defendant Sun Pharmaceutical Industries, Inc. ("Sun").

Pursuant to the contract for the sale of Pharmalucence, Sun agreed to pay Plaintiffs $70 million up front and $30 million in post-closing payments if Plaintiffs achieved milestones related to, in part, the development and regulatory approval of certain products by Pharmalucence.

Plaintiffs now claim that Sun breached the contract by refusing to pay Plaintiffs for certain milestone payments to which Plaintiffs are entitled. The Court held a bench trial from August 30 to September 3, 2021. Having considered the parties' pretrial submissions and the evidence presented at trial, the Court concludes that Plaintiffs have shown by a preponderance of the evidence that Sun triggered Last Man Standing Provision of Schedule 2.4 to the Equity Purchase Agreement (Count II)

and that Plaintiffs are entitled to the milestone payments related to the filing and approval of Mertiatide and Pentetreotide (Count III). Plaintiffs have failed, however, to prove their claims alleging breach of the Capacity Provision (Count IV) and Commercial Reasonableness Provision (Count V), as well as their claim for breach of the implied covenant of good faith and fair dealing (Count VI).

I. *Daubert* Motions

As a preliminary matter, both parties have pending motions to exclude the expert testimony of the opposing party's experts. The Court will address each motion before making its findings of fact and conclusions of law.

A. Legal Standard

1. FRE 702 Generally

Federal Rule of Evidence 702, which governs the admissibility of expert testimony, provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579 (1993), the Supreme Court explained that Rule 702 requires district courts to act as gatekeepers—ensuring that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Id.* at 597. As such, the Court must make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592–93. In short, the Court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same

level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

2. Qualification as Expert

"Rule 702 requires a trial court to make an initial determination as to whether the proposed witness qualifies as an expert." *Baker v. Urban Outfitters, Inc.*, 254 F. Supp. 2d 346, 352–53 (S.D.N.Y. 2003). "Courts within the Second Circuit 'have liberally construed expert qualification requirements' when determining if a witness can be considered an expert." *Cary Oil Co. v. MG Refin. & Mktg., Inc.*, 2003 WL 1878246, at *1 (S.D.N.Y. Apr. 11, 2003) (quoting *TC Sys. Inc. v. Town of Colonie*, 213 F. Supp. 2d 171, 174 (N.D.N.Y. 2002)); *accord Plew v. Ltd. Brands, Inc.*, 2012 WL 379933, at *4 (S.D.N.Y. Feb. 6, 2012). "To determine whether a witness qualifies as an expert, the court must first ascertain whether the proffered expert has the educational background or training in a relevant field." *Crown Cork & Seal Co., Inc. Master Ret. Tr. v. Credit Suisse First Boston Corp.*, 2013 WL 978980, at *2 (S.D.N.Y. Mar. 12, 2013) (citation and internal quotation marks omitted). "Any one of the qualities listed in Rule 702—knowledge, skill, experience, training, or education—may be sufficient to qualify a witness as an expert." *Id.* (citing *Tiffany (N.J.) Inc. v. eBay, Inc.*, 576 F. Supp. 2d 457, 458 (S.D.N.Y. 2007)).

Even if a proposed expert lacks formal training in a given area, he may still have "practical experience" or "specialized knowledge" qualifying him to give opinion testimony under Rule 702. *See McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995) (internal quotation marks omitted) (quoting Fed. R. Evid. 702). But "[i]f the witness is relying solely or primarily on experience, then [he] must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Pension Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC*, 691 F. Supp. 2d 448, 473 n.148 (S.D.N.Y. 2010) (quoting Fed. R. Evid. 702 advisory committee's note). Where a witness's

"expertise is too general or too deficient," the Court "may properly conclude that [he is] insufficiently qualified." *Stagl v. Delta Air Lines, Inc.*, 117 F.3d 76, 81 (2d Cir. 1997).

A court must then "compare the area in which the witness has superior knowledge, education, experience, or skill with the subject matter of the proffered testimony." *United States v. Tin Yat Chin*, 371 F.3d 31, 40 (2d Cir. 2004) (citing *United States v. Diallo*, 40 F.3d 32, 34 (2d Cir. 1994)). "The expert's testimony must be related to those issues or subjects within his or her area of expertise." *Crown Cork*, 2013 WL 978980, at *2 (citing *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 642 (S.D.N.Y. 2007)). "If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent." *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) (citing *Stagl*, 117 F.3d at 80). "Thus, an expert 'should not be required to satisfy an overly narrow test of his own qualifications,' and the court's focus should be on 'whether the expert's knowledge of the subject is such that his opinion will likely assist the trier of fact in arriving at the truth.'" *Crown Cork*, 2013 WL 978980, at *2 (quoting *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 2006 WL 2128785, at *5 (S.D.N.Y. July 28, 2006)). "Assertions that the witness lacks particular educational or other experiential background, 'go to the weight, not the admissibility, of [the] testimony.'" *Zyprexa Prods.*, 489 F. Supp. 2d at 282 (quoting *McCullock,* 61 F.3d at 1044).

3. Expert Testimony Must Assist the Trier of Fact

To be admissible, a district court must conclude that proposed testimony will assist the trier of fact. *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 540 (S.D.N.Y. 2004). "Testimony is properly characterized as 'expert' only if it concerns matters that the average juror is not capable of understanding on his or her own." *United States v. Mejia*, 545 F.3d 179, 194 (2d Cir. 2008); *see also United States v. Amuso*, 21 F.3d 1251, 1263 (2d Cir. 1994) ("A district court may commit manifest error by admitting expert testimony where the evidence impermissibly mirrors the testimony offered

by fact witnesses, or the subject matter of the expert's testimony is not beyond the ken of the average juror.").

"Weighing whether the expert testimony assists the trier of fact goes primarily to relevance." *Faulkner v. Arista Recs. LLC*, 46 F. Supp. 3d 365, 375 (S.D.N.Y. 2014) (citing *Daubert*, 509 U.S. at 591). Relevance can be expressed as a question of "fit"—"whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 591 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)). Expert testimony is not helpful if it "usurp[s] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it." *United States v. Duncan*, 42 F.3d 97, 101 (2d Cir. 1994) (quoting *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991)). Expert testimony that is "directed solely to lay matters which a jury is capable of understanding and deciding without the expert's help" should not be admitted. *United States v. Mulder*, 273 F.3d 91, 101 (2d Cir. 2001) (quoting *United States v. Castillo*, 924 F.2d 1227, 1232 (2d Cir. 1991)).

4. Expert Testimony Must Be Reliable

In assessing reliability, courts should consider "the indicia of reliability identified in Rule 702, namely, (1) that the testimony is grounded on sufficient facts or data; (2) that the testimony is the product of reliable principles and methods; and (3) that the witness has applied the principles and methods reliably to the facts of the case." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002) (citing Fed. R. Evid. 702).

When evaluating the reliability of an expert's testimony, the court must "undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand." *Id.* at 267. If the expert's testimony does not rest on traditional scientific methods, the court may permit testimony "where a proposed expert witness bases her testimony on practical experience

rather than scientific analysis." *Davis v. Carroll*, 937 F. Supp. 2d 390, 412 (S.D.N.Y. 2013). "[T]he reliability inquiry may . . . focus upon personal knowledge and experience of the expert." *Id.*

"In undertaking this flexible inquiry, the district court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district court's belief as to the correctness of those conclusions." *Amorgianos*, 303 F.3d at 266. But as the Supreme Court has explained, "conclusions and methodology are not entirely distinct from one another," and a district court is not required to "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (citation omitted). "Thus, when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos*, 303 F.3d at 266. On the other hand, "[w]here an expert's methodology overcomes the hurdle of being based on a reliable process, remaining controversies as to the expert's methods and conclusions generally bear on the weight and credibility—but not admissibility—of the testimony." *Royal & Sun All. Ins. PLC v. UPS Supply Chain Sols., Inc.,* 2011 WL 3874878, at *2 (S.D.N.Y. Aug. 31, 2011) (citation omitted).

In light of the liberal admissibility standards of the Federal Rules of Evidence, exclusion of expert testimony is warranted only when the district court finds "serious flaws in reasoning or methodology." *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 173 (S.D.N.Y. 2009) (citing *Amorgianos*, 303 F.3d at 267). Otherwise, if an expert's testimony falls within "the range where experts might reasonably differ," the duty of determining the weight and sufficiency of the evidence on which the expert relied lies with the jury, rather than the trial court. *Kumho Tire*, 526 U.S. at 153. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596 (citation omitted). "[T]he proponent of expert testimony has

the burden of establishing by a preponderance of the evidence that the admissibility requirements under Rule 702 are satisfied." *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007) (citing *Daubert*, 509 U.S. at 593 n.10).

If, at the end of the Court's evaluation of these factors, "'some, but not all, of an expert's opinions . . . meet the criteria' of Rule 702 of the Federal Rules of Evidence, then 'a court may exclude portions of an expert report while admitting other portions.'" *Royal Park Invs. SA/NV v. U.S. Bank Nat'l Ass'n*, 324 F. Supp. 3d 387, 394 (S.D.N.Y. 2018) (quoting *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 310 F.R.D. 69, 76 (S.D.N.Y. 2015)).

Testimony that is admissible under Rule 702 may be excluded under Federal Rule of Evidence 403 if the court finds that "the probative value of the evidence is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Expert testimony is particularly susceptible to these dangers, "given to the unique weight such evidence may have in a jury's deliberations." *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005). "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 . . . exercises more control over experts than lay witnesses." *Daubert*, 509 U.S. at 595 (quotations omitted).

B. Motion to Exclude Expert Testimony of Timothy Hanrahan

Defendant seeks to exclude the expert report and testimony of Timothy Hanrahan, a pharmaceutical project consultant. Hanrahan offers two opinions. First, he offers a so-called "Scientific Feasibility Opinion"—that "it was scientifically feasible to develop generic Tetrofosmin 10 and 30 ml products at the [Billerica] Facility within the milestone timeframe." Revised Expert Rep. of Timothy Hanrahan ("Hanrahan Rep."), Dkt. No. 63, Ex. G, ¶ 33. Second, he offers a so-called "Capacity Opinion"—that "the PI facility/development group was operating at or near

capacity after Sun integration (July 2014) and did not have capacity for both its existing projects and transfers from Halol at the same time." *Id.* ¶ 59.

Defendant moves to exclude Hanrahan's testimony, principally arguing (1) that Hanrahan's experience does not qualify him as an expert in the areas in which he opines; (2) that Hanrahan's opinions are not based on a reliable methodology; (3) that Hanrahan's opinions seek to impermissibly usurp the role of the fact finder; and (4) that Hanrahan's Capacity Opinion is irrelevant as it does not address the entire relevant period of time. Mem. of L. in Supp. of Mot. to Exclude the Testimony of Timothy Hanrahan ("Hanrahan Br."), Dkt. No. 62, at 2–3.

1. Hanrahan's Qualifications

In attacking Hanrahan's qualifications, Defendant argues that Hanrahan lacks the experience to render the Capacity Opinion because he has no experience overseeing the operations of an entire pharmaceutical manufacturing and development facility. Hanrahan Br. at 11. Instead, argues Defendant, Hanrahan has experience only in overseeing two products at a contract manufacturing facility. *Id.* at 11. And, otherwise, his experience relates only to consulting on manufacturing equipment. *Id.* at 11–12. Likewise, Defendant argues that Hanrahan lacks the experience necessary to render the Scientific Feasibility Opinion because he has no expertise in the development of radiopharmaceuticals for manufacture at a facility similar to the ones operated by Pharmalucence during the relevant time period (July 2014 through 2017). *Id.* at 16. In particular, Hanrahan has not developed pharmaceutical products since 1991. *Id.* at 16. And Hanrahan admits that he is not familiar with how Pharmalucence's manufacturing process differs from those employed while he was developing pharmaceuticals. *Id.* at 16.

Regarding Hanrahan's qualifications to make the Capacity Opinion, "Rule 702 embodies a 'liberal standard of admissibility for expert opinions.'" *Lion Oil Trading & Transp., Inc. v. Statoil Mktg. & Trading (US) Inc.*, 2011 WL 855876, at *1 (S.D.N.Y. Feb. 28, 2011) (quoting *Nimely*, 414 F.3d at

395). "An expert need not be disqualified 'merely because he or she does not possess experience tailored to the precise product or process that is the subject matter of the dispute.'" *Id.* (quoting *Peretz v. Home Depot*, 2009 WL 3124760, at *2 (E.D.N.Y. Sept. 29, 2009)); *see also Ryan v. Nat. Fire Ins. Co. of Pittsburgh*, 2010 WL 2232670, at *2 (D. Conn. June 2, 2010) ("[L]ack of specific experience in a particular area is not determinative . . . ."). Indeed, the Second Circuit has rejected exclusion of experts based solely on an expert's lack of experience with a specific system. *See, e.g.*, *Stagl*, 117 F.3d at 82 (reversing order excluding expert despite expert's admitted lack of experience with the specific kind of system at issue). Instead, "to find an expert unqualified, the court must find the expert's general experience insufficient . . . to testify about the issue in the case at hand." *Ryan*, 2010 WL 2232670, at *2.

Here, Hanrahan has experience in the development and manufacturing of radiopharmaceuticals, including experience in "new product development," supervision of a "development pilot plant," "resolution of product production issues," and "product technology transfer[s]." Hanrahan Rep. ¶ 5. While Hanrahan has not operated an entire facility, he has experience in the development of radiopharmaceuticals. Hanrahan possesses the general experience required to testify regarding the Capacity Opinion.

Absent a showing of insufficient general experience, the lack of specific experience properly goes to the weight, rather than the admissibility, of an expert's testimony. *See McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995) (expert's lack of experience performing or interpreting air quality studies was "properly explored on cross-examination and went to his testimony's weight and credibility—not its admissibility"); *see also Emig v. Electrolux Home Prod. Inc.*, 2008 WL 4200988, at *5 (S.D.N.Y. Sept. 11, 2008) (finding that "the facts that [the expert] ha[d] no post-graduate degree in engineering and that he lack[ed] experience in the particular area of consumer products go to the weight, and not the admissibility, of his testimony and can be properly explored on cross-

examination"). Thus, while the Court evaluates Hanrahan's experience in this area in weighing his testimony, it is not sufficient grounds for its exclusion.

Hanrahan also has the qualifications necessary to make the Scientific Feasibility Opinion. Defendant argues that because Hanrahan's development experience took place "over thirty years ago" and that "he is not familiar with how processes related to the drugs he developed have changed," Hanrahan is not qualified as an expert. Reply Mem. of L. in Further Supp. of Mot. to Exclude the Testimony of Timothy Hanrahan ("Hanrahan Reply Br."), Dkt. No. 81, at 7. As Plaintiffs correctly point out, however, the Second Circuit has found that the age of an expert's experience is a matter of weight rather than admissibility. *See Cunningham v. Gains*, 507 F.2d 496, 500 (2d Cir. 1974) (rejecting objection to expert where "some of his experience in the field had taken place many years ago" and finding that "defendants are free to cross-examine [the expert] to develop any shortcomings in his qualifications"). Defendant urges this Court to distinguish this case from *Cunningham* because Hanrahan has not continued working as a development scientist and cannot identify how the development process may have changed over the years. This Court declines to do so. These are reasonable critiques, and the Court considered them in weighing Hanrahan's testimony. However, Plaintiffs have made a sufficient showing that Hanrahan has the qualifications required for him to render his opinion. Hanrahan is qualified to testify regarding the Scientific Feasibility Opinion.

2. Hanrahan's Methodology

Defendant next argues that the methodologies Hanrahan employed to reach the Capacity and Scientific Feasibility Opinions are unreliable and require exclusion. Hanrahan Br. at 12–13, 20.

A "district court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district court's belief as to the correctness of those conclusions." *Amorgianos*, 303 F.3d at 266. But "conclusions and methodology

are not entirely distinct from one another," and a district court is not required to "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146. "Thus, when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusion reached, *Daubert* and Rule 702 mandate [exclusion]." *Amorgianos*, 303 F.3d at 266.

Further, "an expert basing his opinion solely on his experience must do more than aver conclusorily that his experience led to his opinion: '[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.'" *523 IP LLC v. CureMD.Com*, 48 F. Supp. 3d 600, 643 (S.D.N.Y. 2014) (quoting *Pension Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC*, 691 F. Supp. 2d 448, 473 n.148 (S.D.N.Y. 2010) (quoting Fed. R. Evid. 702 advisory committee's note)).

i. Capacity Opinion Methodology

Regarding the Capacity Opinion, Hanrahan avers that "[a]llocating development and manufacturing resources . . . involves weighing the costs, benefits and risks of the competing potential projects, evaluating relevant timelines, and prioritizing some projects over others." Hanrahan Rep. ¶ 61. But Hanrahan undertakes no such analysis himself.

Instead, Hanrahan's method consists of evaluating the credibility of "several internal emails . . . concerning PI-Sun capacity." *See id.* ¶¶ 63, 65. In each instance, Hanrahan reviews an email, interprets what was written, evaluates whether he believes that what was written is credible, and restates what was written in the email as his expert conclusion. Next, Hanrahan bases a number of statements on a review of Pharmalucence/Sun time sheets for 2014 and 2015 relating to the development of the tetrofosmin 10 and 30 ml products. *Id.* ¶¶ 60, 66. As with the internal emails, Hanrahan merely summarizes the documents without any application of expertise. Hanrahan

describes the percentage of hours the Pharmalucence development team spent on the milestone products before and after the transfer of Sun products in fall 2014. *Id.* ¶ 66. But nowhere does Hanrahan apply his experience to describe what this data means. Finally, Hanrahan avers that he reviewed Pharmalucence organizational charts for the Development Group. *Id.* ¶ 68. Hanrahan notes that the headcount for the Development Group "remained roughly unchanged" from June 2014 to June 2015. *Id.* ¶ 68. And also notes that the June 2015 chart shows four open positions, "indicating that the Development Group required additional resources around that time." *Id.* ¶ 68. As with the other materials, Hanrahan fails to reference his experience or expertise to indicate that these observations are anything more than the rational perception of a lay person based on a review of the documents.

In the end, Hanrahan's methodology "amounts to no methodology at all." *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 502 (S.D.N.Y. 2018). Indeed, "[i]n the absence of some recognizable, describable methodology beyond an appeal to [the expert's] qualifications" an opinion based on this methodology "would be 'the essence of unverifiable subjectivity, amounting to the sort of *ipse dixit* connection between methodology and conclusion' that is properly excluded." *Id.* (quoting *Nimely*, 414 F.3d at 399). Accordingly, Hanrahan's Capacity Opinion is excluded for failing to apply reliable principles and methods.

ii. Scientific Feasibility Opinion Methodology

Hanrahan's Scientific Feasibility Opinion actually comprises a number of separate opinions. The ultimate opinion reached by Hanrahan is that "[i]t was scientifically feasible to develop generic Tetrofosmin 10 and 30 ml products at the Facility within the milestone timeframe." Hanrahan Rep. ¶ 33. But this opinion is founded on four separate conclusions: (1) that the tetrofosmin development did not have any significant/uncommon issues; (2) that the line filler at the Billerica Facility could handle the production of oxygen and light-sensitive products; (3) that the challenge

associated with acquiring the necessary API for Tetrofosmin development was "not insurmountable"; and (4) that the Tetrofosmin Project Timeline developed by Paul Damphousse in June 2015 was a reasonable schedule. *Id.* ¶¶ 39, 44–45, 52–53, 55.

First, Hanrahan posits that, in his understanding, "the [tetrofosmin] 10 ml development work did not encounter any significant challenges." *Id.* ¶ 39. Hanrahan supports this conclusion with application of his expert experience to make observations and provide analysis, rather than simply parroting the contents of documents. *See, e.g.*, Hanrahan Rep. ¶ 42 ("I have two observations on this"); ¶ 42(b) ("This indicates that . . . ."). Most notably, Hanrahan supports his conclusion with the observation that:

> It is not uncommon to have limited quantity of API when performing developmental work; however[,] the quality of the API is critical for the accurate evaluation of the studies performed (e.g.[,] solution stability). Issues with API supply are not uncommon and can be addressed if the decision is made to devote sufficient resources to developing API handling and storage procedure, monitoring API stability and re-ordering API (long lead syntheses) for continuity of development work.

Id. ¶ 44. These observations are evidently, though not explicitly, based on Hanrahan's expert experience. A lay person would not know whether such issues were common. As such, Hanrahan applies a valid method to this part of his opinion.

Second, Hanrahan concludes that "the Facility's filling line had existing systems in place to address [oxygen and light sensitive products]. The vial filler, manufactured by Bosch, was designed and tested for oxygen and light sensitive." *Id.* ¶ 54. Hanrahan makes these observations without reference to any internal Pharmalucence documents, suggesting that they are based on his experience as a consultant installing pharmaceutical manufacturing equipment.

Third, Hanrahan posits that "the challenge associated with acquiring the necessary API for tetrofosmin development was 'not insurmountable' for PI." *Id.* ¶ 45. This statement is based on Hanrahan's review of documents concerning Pharmalucence's issues acquiring API for two other

products, as well as the application of his previous experience with developing radiopharmaceuticals. Thus, the Court will not exclude the entire Scientific Feasibility Opinion. Instead, the weight of the remainder of the Scientific Feasibility Opinion depends on whether Plaintiffs are able to otherwise establish that the API issues were not insurmountable.

Finally, Hanrahan's analysis of the Damphousse timeline is based on his expert experience. *Id.* ¶ 57. While Defendant takes issue with the timeline because Damphousse later disavowed its accuracy, (Hanrahan Br. at 19–20), Hanrahan's analysis looks to whether the timeline is reasonable given his experience in product development, not to whether Damphousse believed it was reasonable at the time, which appears to be a valid application of his experience. Defendant sufficiently explored these issues on cross-examination and the Court will give this opinion its due weight.

3. Whether Hanrahan's Testimony Will Assist the Trier of Fact

i. The Capacity Opinion

Hanrahan's ultimate conclusion in his Capacity Opinion is that "the PI facility/development group was operating at or near capacity after Sun integration (July 2014) and did not have capacity to both develop its existing projects and accommodate transfers from Halol at the same time." Hanrahan Rep. ¶ 67. As discussed earlier, this conclusion is not based on reliable principles and methods. But it is likewise excludable because it fails to "assist the trier of fact to understand the evidence or determine a fact in issue." *Daubert*, 509 U.S. at 591. Instead, the Capacity Opinion merely summarizes Hanrahan's reading of internal emails and documents. "The proposed testimony pertains to 'lay matters which a [finder of fact] is capable of understanding and deciding without the expert's help.'" *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 554 (S.D.N.Y. 2004) (quoting *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989)). And "is no more than 'arguments and conclusory statements about questions of fact masquerading behind a veneer' of

expertise." *Id.* at 554 (quoting *LinkCo, Inc. v. Fujitsu Ltd.*, 2002 WL 1585551, at *2 (S.D.N.Y. July 16, 2002)); *see also Syntel Sterling Best Shores Mauritius Ltd. v. Trizetto Grp.*, 2020 WL 5822064, at *2 (S.D.N.Y. Sept. 30, 2020) (excluding testimony where the expert "merely state[d] a legal conclusion . . . based on a review of emails and presentations that a jury can conduct"). The Court can evaluate the documents to evaluate what Pharmalucence employees believed about the facility's capacity—Hanrahan's purported opinions will not assist the Court in evaluating that evidence. Instead, he offers conclusions that displace those of the finder of fact.

Finally, while not necessary to address given the exclusion of Hanrahan's Capacity Opinion, Defendant challenges the relevance of Hanrahan's Capacity Opinion. According to Defendant, Hanrahan's Capacity Opinion is irrelevant because it only shows, at most, capacity at a fixed point in time, not capacity throughout the relevant time period. This argument misunderstands relevance. Evidence is relevant where "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. While it is true that the Capacity Opinion only looks at a limited point in time, it indisputably looks to a point in time that is "of consequence" to the action. As such, it is relevant to show, at least for that limited time period, that Pharmalucence had, or did not have, capacity to take on additional projects. The bar for relevance does not require that a single witness or exhibit address the entire time period in order to be admissible.

ii. The Scientific Feasibility Opinion

Hanrahan's Scientific Feasibility Opinion will provide insight into the industry and will assist the fact finder with matters beyond a lay person's understanding. Understanding the typical obstacles in the development process, as well as when those obstacles are or are not insurmountable, will assist the tier of fact in determining whether Defendant took commercially reasonable actions in developing the Tetrofosmin Products.

4. Weight of Hanrahan's Testimony

While much of Hanrahan's testimony is admissible, it is entitled to very little weight. As revealed on cross-examination, Hanrahan conducted no tests of Pharmalucence's equipment under real-world conditions, did not analyze the chemical makeup of tetrofosmin, and did not undertake any independent comparison of tetrofosmin with other products manufactured by Pharmalucence. Hanrahan's bachelor's degree in chemistry does not evidence the expertise of a PhD such as Dr. Horn. And Hanrahan's experience as a chemist is quite dated. Hanrahan's experience in developing radiopharmaceuticals is also dated. And he conducted no analysis to ensure his experience was compatible with current methods. Moreover, Hanrahan admitted that he was close personal friends with Connolly—attending concerts and sporting events; traveling with one another; and golfing together. Such obvious bias paired with the near complete lack of independent analysis, limited educational credentials, and the fact that much of Hanrahan's relevant experience is very long in the tooth, leads the Court to give very little weight to Hanrahan's testimony. In short, while admissible under *Daubert*, the Court largely finds Hanrahan's testimony to be not credible. Plaintiffs chose a golfing buddy as their expert—one with limited academic credentials, dated experience and who chose to conduct no independent scientific analysis. While the Court's conclusion here regarding Hanrahan's credibility was not foreordained, it could have been foreseen.

C. Motion to Exclude Expert Testimony of Dr. Mark Robbins

Next, Plaintiffs seek to exclude the expert testimony of Dr. Mark Robbins, a pharmaceutical consultant. Robbins offers two opinions. First, he opines on "(a) whether Sun exercised commercially reasonable efforts to develop generic tetrofosmin 10 cc and generic tetrofosmin 30 cc cold kits . . . and (b) whether it was commercially reasonable for Sun not to restart development of the Tetrofosmin Products . . . in the fall of 2014." Expert Rep. of Mark Robbins, Ph.d., J.D. ("Robbins Rep."), Dkt. No. 144, ¶ 5. Second, he opines on "whether, by attempting to transfer products from Sun's facility in Halol, India to Pharmalucence's facility in Billerica, Massachusetts,

Sun materially diminished the manufacturing and/or development capacity of Pharmalucence's facilities" to develop the milestone products. *Id.* ¶ 6. That is to say, he offers a "Capacity Opinion" similar to Hanrahan.

As an initial matter, the Court must address Plaintiffs' claim that Robbins relied on information based on an interview with Paul Damphousse in violation of this Court's order at Dkt. No. 115. Pls.' Mem. of Law in Supp. of Their Daubert Mot. to Exclude Mark Robbins' Expert Testimony and Strike Expert Report ("Robbins' Br."), Dkt. No. 144, at 3. In that order, the Court directed that "the substitute expert may only review materials that were available to Mr. Zisa; and the substitute expert may only rely on materials relied upon by Mr. Zisa." Dkt. No. 115. Defendant counters that this Court's order did not limit the *facts* Robbins could rely on, but only the *materials*. Def.'s Mem. of Law in Opp'n to Pls.' Daubert Mot. to Exclude Mark Robbins Expert Testimony and Strike Expert Report ("Robbins Opp'n"), Dkt. No. 145, at 2. Ultimately, while the Defendant's maneuver is not in the spirit of the Court's order—Defendant's interpretation of the order is quite sharp, as is, arguably, its decision to proceed in this way—it did not technically violate the order. That said, any possible prejudice was mitigated by Plaintiffs comprehensive cross-examination of Robbins at trial. And Hanrahan was able to address Robbins' conclusions on redirect.

As to the substance of the report and testimony, Plaintiffs do not challenge Robbins' qualifications. This is prudent because Robbins is clearly qualified by virtue both of his educational history and his professional experience. Instead, Plaintiffs argue that (1) Robbins was impermissibly assigned to opine on legal conclusions; (2) Robbins' methods were unreliable; and (3) Robbins' opinions will be unhelpful to the fact finder. Robbins Br. at 2–4.

1. Capacity Opinion

Robbins' Capacity Opinion is largely excluded for the same reasons as Hanrahan's Capacity Opinion—it is little more than a factual narrative with references to internal emails and deposition

transcripts. *See* Robbins' Rep. ¶¶ 65–76, 79. Nowhere in his analysis does Robbins opine on—or apply—his experience to the materials. His Capacity Opinion basically provides a factual narrative. And that factual narrative does not build up to a properly offered expert opinion. As Robbins is merely narrating the facts that were put to the Court by fact witnesses, his Capacity Opinion is excluded for failing to apply reliable principles and methods. *See In re LIBOR-Based Fin. Instruments*, 299 F. Supp. 3d at 502. It is also properly excluded because by providing a narration of the facts, the aspects of his report usurp the role of the fact finder. As with Hanrahan's Capacity Opinion, this opinion seeks to expertize what, at bottom, is a lay fact issue to be addressed by the fact finder.

The Court will not, however, exclude testimony describing industry practice, such as testimony that it is "typical to assign individuals in a development organization to work on multiple projects," and that "Pharmalucence utilized its development staff in accordance with common practices in the pharmaceutical industry by assigning multiple projects per individual with a range of one to four projects assigned per individual." Robbins Aff. ¶¶ 106–07. This type of testimony is helpful for the Court in evaluating the facts presented.

2. Commercial Reasonableness Opinion

Plaintiffs first argue that Robbins' Commercial Reasonableness Opinion should be disqualified "*ab initio*" because Defendant's assignment to Robbins asks him to draw a legal conclusion. Robbins Br. at 17. In support of this rule, Plaintiffs cite to *Primavera Familienstifung v. Askin*, 130 F. Supp. 2d 450, 528 (S.D.N.Y. 2001) *amended on reconsideration in part*, 137 F. Supp. 2d 438 (S.D.N.Y. 2001), *and abrogated on other grounds by Casey v. Merck & Co.*, 653 F.3d 95 (2d Cir. 2011). In response, Defendant avers that it is required to provide this type of expert testimony, (Robbins Opp'n at 8–9), pointing to this Court's ruling in *Holland Loader Co., LLC v. FLSmidth A/S*, 313 F. Supp. 3d 447, 472–73 (S.D.N.Y. 2018), *aff'd*, 769 F. App'x 40 (2d Cir. 2019).

Both parties misinterpret their respective cases. The court in *Primavera* did not find that an assignment to an expert calling for a legal conclusion makes the expert's report and testimony void *ab initio* in its entirety. Rather, the court noted that the report at issue was "flawed from the outset" as a way of emphasizing the extensive nature of the issues with the expert's report. *See Primavera*, 130 F. Supp. 2d at 529 ("Given Malkiel's assignment, it is perhaps unsurprising that the Malkiel report is permeated with inadmissible legal opinions and conclusions directed at telling the jury what result to reach."). Indeed, far from striking the report as invalid from the outset, the court conducted a straightforward *Daubert* analysis of the report and, while excluding most of the report for making impermissible legal conclusions, excluded other portions for making conclusory assertions of fact. *See id.* at 529–30. As a result, the Court does not read *Primavera* to establish a categorical bar based on the question posed to the expert in his assignment. Conducting an in-depth analysis rather than crafting a bright-line exclusionary rule based only on an expert's assignment seems appropriate, as a rule excluding a report without analyzing its contents for admissible material would run counter to caselaw allowing a trial court to "exclude portions of an expert report while admitting other portions." *Royal Park Invs.*, 324 F. Supp. 3d at 394 (quotation marks omitted).

Nor does this Court's finding that "courts in this district require the party seeking to enforce the efforts provision to establish the objective standard by which the breaching party's efforts are to be judged" give a party license to insert improper legal conclusions into an expert report. *Holland Loader*, 313 F. Supp. 3d at 472. Indeed, the rule quoted from *Holland Loader* requires a party to establish an objective standard by which the trier of fact can determine an outcome. It does not require—or enable—a party to submit an expert opinion regarding the ultimate issue in the case. As has always been the case, experts are not allowed to opine on the ultimate question of whether a party has breached the terms of a contract, even when that contract calls for following an industry custom or practice on which that expert may opine:

> Although [an expert's] proposed testimony to establish prevailing customs and practices in . . . [an] industry is relevant and reliable and would be admissible for that purpose, he may not go so far as to opine as to whether certain events constituted a material breach of the Credit Agreement. That testimony would constitute an impermissible opinion as to an ultimate legal conclusion in this case.

CIT Grp./Bus. Credit, Inc. v. Graco Fishing & Rental Tools, Inc., 815 F. Supp. 2d 673, 678 (S.D.N.Y. 2011) (citation omitted).

Nearly all of Robbins' proposed testimony falls on the right side of the line. Robbins' report details the considerations of industry participants in making certain commercial decisions. *See, e.g.*, Robbins Rep. ¶ 18 (listing factors generally assessed in development projects); ¶ 32 (listing factors considered in deciding whether to modify equipment). Robbins lays out his analysis of those factors—including the tradeoffs associated with many of the individual decisions made by company officials that led to its decision not to pursue tetrofosmin. The bulk of the statements offered in connection with his "Commercial Reasonableness" opinion are based on a reliable methodology and are helpful to the trier of fact.

In several places, however, Robbins offers a specific opinion regarding the "commercial reasonableness" of Defendant's actions—an opinion that, when framed in that way, seems to cross into the realm of legal conclusion. Robbins' opinions regarding the commercial reasonableness of Defendant's actions are carefully framed so that they do not specifically address the ultimate legal question—whether Defendant used commercially reasonable efforts as required under the contract. Instead, Robbins evaluates each individual commercial decision made by the company against the factors that he has described as those considered in industry. *See, e.g.*, Robbins Rep. ¶ 38 ("It was commercially reasonable for Pharmalucence to not modify the Equipment Kit because it would have required significant work, time, and expense and would have required Pharmalucence to delay commercial activities for 1–2 years at the Billerica facility."). And Robbins described that the term "commercially reasonable" is a term of art used in the industry, as well as the legal term used in the

agreement at issue here. However, Robbins adds up these individual conclusions to reach the ultimate issue: "Based on my experience and review of the documents, I conclude that it was commercially reasonable for Pharmalucence to discontinue the development of the Tetrofosmin Products in 2014, and it was commercially reasonable for Sun not to restart development of the Tetrofosmin Products in 2015." *Id.* ¶ 13.

A conclusion regarding the defendant's compliance with a legal standard is not within the bailiwick of an expert. But the Court recognizes that experts can opine on mixed questions of fact and law. *See Fiataruolo v. United States*, 8 F.3d 930, 941 (2d Cir. 1993). At oral argument, Sun's counsel proffered that "commercial reasonableness" is a term in the pharmaceutical industry and that Robbins is opining on what the standard commercial reasonableness means in the pharmaceutical industry, *i.e*,. what is standard industry practice, and whether Sun complied with that standard, *i.e.*, whether Sun's actions were consistent with standard industry practice. Robbins confirmed this representation at trial. So, while the question of whether the conduct was commercially reasonable under the terms of the contract is a determination ultimately reserved for the Court, Robbins' testimony is intended to be shorthand for a description of his assessment of how these factors would be viewed objectively in the relevant industry.

As a result, the Court understands Robbins' opinion to provide his view regarding the industry standard of conduct with respect to each of those commercial decisions. Robbins has identified the reasoning for each of those conclusions, and illustrated how he, as an expert in the field, evaluates the relevant factors confronted by Defendant. These opinions are sufficiently founded in an ascertainable methodology and they are useful to the finder of fact. The Court does not accept Robbins' opinion regarding the ultimate issue to be decided here. The Court is mindful that this is not a jury trial and has little concern that it will be confused or misled into displacing Robbins' opinions—which are meant to help the trier of fact understand how a person in the

industry evaluates the decisions confronted by Defendant—with the ultimate fact that must be decided by the Court.

D. Motion to Exclude Expert Testimony of Dr. Ian Horn

Finally, Plaintiffs seek to exclude the expert testimony of Dr. Ian Horn, a pharmaceutical consultant. Horn offers one bottom-line opinion: whether it would have been commercially reasonable for Pharmalucence to develop and manufacture the tetrofosmin products. Expert Rep. of Dr. Ian M. Horn, FRSC ("Horn Rep."), Dkt. No. 60, ¶ 10. Horn was also asked to respond to certain portions of Hanrahan's expert report. *Id.* ¶ 10. But the principal purpose of Horn's testimony was to explain the scientific and technical difficulties associated with developing tetrofosmin, and to explain those difficulties in the context of a cost-benefit analysis typical in the pharmaceutical industry. *See, e.g.*, Horn Rep. ¶¶ 10, 79–84, 89, 91.

Like Robbins, much of Horn's testimony skirts the line between permissible expert testimony and improper opinion on a legal conclusion. Primarily, Horn's testimony addresses the technical difficulties in developing tetrofosmin, the likely costs to fully develop the products, and considerations of industry participants in making certain commercial decisions. *See, e.g.*, Horn Rep. ¶ 73–92 (describing likely technical difficulties of developing tetrofosmin at the Billerica Facility). At the end of such analysis, however, Horn, concludes that it would not be commercially reasonable for the company to take such actions. *See, e.g.*, Horn Rep. ¶ 93 ("[I]t would not have been commercially reasonable to modify existing equipment or acquire and install a new fill line.")

While defense counsel's proffer related only to Robbins' testimony, the Court construes Horn's use of "commercially reasonable" in the same way—that it is an industry term of art used to describe actions consistent with standard industry practice, rather than a conclusion regarding the meaning of the contract itself. On this basis the Court accepts Horn's testimony.

Separately, Plaintiffs take issue with Horn's conclusions "that there was no reliable source" of tetrofosmin API and that tetrofosmin required an inert manufacturing environment. Pls.' Mem. of Law in Supp. of Their Daubert Mot. to Exclude Def.'s Expert Testimony and Strike Expert Reps. ("Horn Br."), Dkt. No. 60, at 18, 21; Horn Rep. ¶¶11; 64–72.

First, Horn's assertion that there was no reliable source of API is a determination best left to the fact finder. As such it is excluded. However, Horn's assertions regarding the difficulty of obtaining API from suppliers with no prior experience is based on an application of Horn's expert experience. Horn Rep. ¶ 70 ("I have experience retaining API suppliers to develop manufacturing processes for APIs for which they had no prior experience. These projects, in my experience, are not always successful."); *see also* Horn Aff. ¶ 69. As such, the Court accepts this testimony.

Second, Plaintiffs' arguments for excluding Horn's assertions to the effect that "tetrofosmin is unstable in an oxygen environment" are based principally on Horn's inability to explain how GE Healthcare is able to successfully manufacture tetrofosmin. Horn Br. at 22. This argument, to the extent it shows anything, goes to weight, not admissibility. Plaintiffs also claim that Horn bases this assertion only on the conclusions of fact witnesses. *Id.* at 22–23. But Horn takes the conclusions of fact witnesses and applies his experience to them. *See, e.g.*, Horn Rep. ¶ 88 (noting that "[t]he two modifications considered by Damphousse may indeed mitigate degradation of tetrofosmin.").

E. Conclusion

For the forgoing reasons, Defendant's motion is granted with respect to the Capacity Opinion. Plaintiffs' motion to exclude the testimony and report of Robbins is granted with respect to his Capacity Opinion. Plaintiffs' motion to exclude the testimony and report of Horn is granted with respect to Horn's conclusion that there was no reliable source of API for Pharmalucence.

II. MOTIONS TO STRIKE

At trial, the parties moved to strike certain portions of the testimony of Paul Damphousse, Lynne Sole, Daniel O'Brien, and Todd Tessier as improper lay opinion testimony. The parties argue that where these witnesses testify as to the science of developing tetrofosmin and other radiopharmaceuticals they are in fact improperly testifying as experts.

"Rule 701 requires lay opinion testimony to be based on the witness's personal perceptions. The traditional objective of the rule is, after all, to afford the trier of fact 'an accurate reproduction of the event at issue.'" *United States v. Garcia*, 413 F.3d 201, 211 (2d Cir. 2005) (citations omitted). "A witness's specialized knowledge, or the fact that he was chosen to carry out an investigation because of this knowledge, does not render his testimony 'expert' as long as it was based on his 'investigation and reflected his investigatory findings and conclusions, and was not rooted exclusively in his expertise.'" *United States v. Rigas*, 490 F.3d 208, 224 (2d Cir. 2007) (quotation marks omitted); *U.S. ex rel. Tiesinga v. Dianon Sys., Inc.*, 240 F.R.D. 40, 42–43 (D. Conn. 2006) (disallowing questioning of 30(b)(6) witness who happened to be a doctor where questioning went beyond the facts known to the witness and organization and instead asked the witness to opine on the conclusions of the opposing parties' expert). That is to say, a witness with specialized knowledge may testify to facts known to the witness at the time of the events at issue but may not go beyond those facts to apply their expertise. *See, e.g., DVL, Inc. v. Gen. Elec. Co.*, 811 F. Supp. 2d 579, 591 (N.D.N.Y. 2010), *aff'd sub nom. DVL, Inc. v. Niagara Mohawk Power Corp.*, 490 F. App'x 378 (2d Cir. 2012).

That a witness is acting as a supervisor makes no difference. A witness may testify to their rationally based perceptions and personal knowledge gained as supervisors of Pharmalucence's development efforts. *See Medforms, Inc. v. Healthcare Mgmt. Sols., Inc.*, 290 F.3d 98, 111 (2d Cir. 2002) (admitting lay opinions based on perceptions of a supervisor); *Fendi Adele S.R.L. v. Filene's Basement,*

Inc., 696 F. Supp. 2d 368, 382 (S.D.N.Y. 2010) (admitting lay opinions where director "supervised the preparation of the Authenticity Report").

But what to do when the issues at trial require scientists to describe the results of their past work? Critically, here, whether or not the results of the experiments or the conclusions drawn therefrom were accurate is not at issue in this case, as such an analysis would improperly drift into the realm of hindsight. *See Holland Loader Co.*, 313 F. Supp. 3d at 472–73 ("A court's evaluation of a party's compliance with a 'commercially reasonable efforts' requirement does not involve a hindsight comparison of the party's actual conduct to that which could have been undertaken to produce a better result; a court should evaluate only whether the party's actual conduct was sufficient.") Instead, the issue in this case is what conclusions Pharmalucence and Sun drew from the efforts and conclusions of the Pharmalucence development group. As such, testimony regarding these efforts is not providing an expert opinion at all, but rather simply reporting historical events. The distinction is critical. Where the witness is testifying regarding experiments they conducted at the time and the conclusions drawn therefrom—again, at the time—that testimony shows the parties' contemporaneous understanding and belief in the likely success of development efforts. Such testimony is critical in assessing whether Sun acted in a commercially reasonable manner. However, if the witness is testifying as to whether those experiments were correct, thus applying their scientific knowledge to historical facts to draw conclusions, that witness is testifying as an expert and must make the proper disclosure under Federal Rule of Civil Procedure 26(a)(2). Notably, in this case, whether the results of the experiments were correct is not an important inquiry. If the development team, Plaintiffs, and Sun, all believed that further development efforts were infeasible, and made otherwise reasonable decisions based on that belief, whether that belief was accurate does not change the reasonableness of those actions. It is—of course—not commercially reasonable to proceed with efforts a company believes are futile. This principle is especially important in the

context of developing generic products. Here, it is indisputably feasible to develop and manufacture tetrofosmin. GE has been doing so since the 1990s after all. The question is whether Pharmalucence could replicate this success. And testimony that their efforts were not successful is both highly relevant and not based on expertise. Indeed, none of the experts in this case could testify as to what these witnesses believed and communicated based on those beliefs, as that would improperly usurp the role of the fact finder. Indeed, when the experts in this case attempted to do so in their capacity opinions the Court excluded them as improper.

As a result, Damphousse, Sole, O'Brien, and Tessier may testify to their knowledge of the facts at the time of the events at issue. They may also testify as to how their experience informed their understanding at that time. These witnesses may not, however, apply their expertise to information they were not aware of at the time of the events in order to draw conclusions or opinions. Such testimony is only appropriate when made by a properly designated expert.

Having reviewed the objected to testimony, the Court denies the motions to strike except as to the following: Damphousse Aff. ¶¶ 25, 26 & 40; Sole Aff. ¶ 26, 27, 33, 34, and 40 except for the sentence beginning with "therefore, during my employment . . ."; O'Brien Aff. ¶¶ 23, 24 & 25; Tessier Dep. Tr. 82:4–16; 84:12–17; 84:18–85:17.

III. FINDINGS OF FACT

Pursuant to Rule 52(a) of the Federal Rules of Civil Procedure, the Court makes the following findings of fact[1] and conclusions of law.

A. The Parties

Plaintiff Glenn Alto is an individual who resides in, and is a citizen of, the Commonwealth of Massachusetts. Alto joined Pharmalucence, then known as CIS-US, in 1991 as a Product Manager and subsequently rose to the position of Executive Vice President and Chief Operating

[1] These facts have been proven by a preponderance of the evidence.

Officer. Following Plaintiffs' management buyout in 2007, Alto became the Chief Executive Officer of Pharmalucence.

Plaintiff Edward Connolly is an individual who resides in, and is a citizen of, the Commonwealth of Massachusetts. Connolly joined Pharmalucence, in 1997 as the Director of Operations with direct responsibility for Pharmalucence's then-sole production facility. Following Plaintiffs' management buyout in 2007, Connolly became the Chief Operating Officer of Pharmalucence.

Plaintiff Lewis Waters is an individual who resides in, and is a citizen of, the Commonwealth of Massachusetts. Waters joined Pharmalucence in 2000 as Corporate Controller. Following Plaintiffs' management buyout in 2007, Waters became Pharmalucence's Chief Financial Officer. Waters is also the trustee of the Lewis William Waters III 2014 Qualified Annuity Trust, which is a grantor formed annuity trust formed in the Commonwealth of Massachusetts and is a party to the Equity Purchase Agreement described in detail below.

Defendant Sun Pharmaceutical Industries, Inc. ("Sun") has a principal place of business in New Jersey. Sun is ultimately owned by Sun Pharmaceutical Industries Ltd. ("SPIL"), which is headquartered in India. Sun develops, licenses, manufactures, markets, and distributes generic, prescription, and over-the-counter pharmaceuticals.

B. Pharmalucence

Pharmalucence Inc. ("Pharmalucence"), n/k/a Sun Radiopharma, is a Massachusetts-based company with a manufacturing facility located in Billerica, Massachusetts. Pharmalucence began as a company called CIS-US and was acquired by Plaintiffs in a management buyout in 2007. Plaintiffs were the sole owners of Pharmalucence until it was acquired by Sun in July 2014 (the "Acquisition").

Pharmalucence manufactures a line of generic, injectable radiopharmaceuticals, called "cold kits." Cold kits generally consist of a drug substance combined in a lyophilized (freeze-dried) formulation along with associated buffers and excipients. When cold kits are combined with a

radioisotope, they form a radiopharmaceutical used in nuclear medicine diagnostic procedures. Pharmalucence and others in the industry colloquially refer to the drug substance in these products as the "active pharmaceutical ingredient" or "API." The different APIs used in cold kits cause the radiopharmaceutical to be absorbed by different kinds of cells in a patient's body—highlighting those cells in images produced by medical imaging equipment.

Pharmalucence does not have the ability to manufacture the radioisotopes that are combined with the cold-kit products or the API included in its cold kit products. Because Pharmalucence does not have the ability to produce API, it must obtain APIs from outside vendors in order to manufacture its products.

At the time of the Acquisition, Pharmalucence had two manufacturing facilities: one older facility located in Bedford, Massachusetts (the "Bedford Facility") and one new facility located in Billerica, Massachusetts (the "Billerica Facility," and, together with the Bedford Facility, the "Pharmalucence Facilities"). Plaintiffs had determined to design and build the Billerica Facility because the Bedford Facility was at high risk for falling behind evolving FDA regulatory guidance.

At the time of the Acquisition, Pharmalucence sold the following products: sulfur colloid, mebrofenin, medronate, sestamibi, pyrophosphate, and hepatolite. At the same time, Pharmalucence was in the process of developing four additional generic radiopharmaceutical products: mertiatide; tetrofosmin in a 10 cc vial ("tetrofosmin 10 cc"); tetrofosmin in a 30 cc vial ("tetrofosmin 30 cc"), and pentetreotide. In addition to the manufacture and development of its own products, Pharmalucence engaged in contract development and manufacturing.

C. Negotiation of the Acquisition

In 2013, Plaintiffs retained investment bank Covington Associates ("Covington") to pursue a sale of Pharmalucence. The primary Covington investment banker assisting Pharmalucence was Scott Fisher. Covington marketed Pharmalucence for potential sale, making potential buyers aware of Pharmalucence's new Billerica Facility, radiopharmaceutical experience, and contract

manufacturing business. Covington understood that most potential buyers would not be interested in continuing with contract manufacturing, so its marketing highlighted one of the company's core competencies—that Pharmalucence's development team had the experience and proficiency to develop and/or manufacture products from outside of its own portfolio. Potential buyers would be attracted by the opportunity to transfer their own products to the Billerica Facility, which had more manufacturing capacity than would be used by Pharmalucence's current products, using Pharmalucence's resources and expertise.

In the course of its work, Covington determined that Pharmalucence's valuation was roughly $100 million. Covington reached that figure by using an early offer Pharmalucence received from a prospective buyer. Valuing Pharmalucence was complicated owing to the fact that the company had just made a significant capital investment in a new, significantly larger manufacturing facility that was not yet online. Thus, the value of Pharmalucence could not be assessed accurately based solely on past sales and profits from the products in its portfolio.

Pharmalucence received buyer interest from at least four companies, including Sun. Besides Sun, at least one potential buyer was interested in an earn-out/milestone payment structure. In late 2013 and early 2014, Sun emerged as a serious potential buyer of Pharmalucence. Sun was particularly interested in transferring some of its existing products from its production facilities in India to the Billerica Facility. As of at least January 11, 2014, Sun was aware that Pharmalucence was planning to develop four new radiopharmaceutical products. And Sun expected that those products could significantly increase Pharmalucence's revenue if they were successfully developed. However, Sun believed that Pharmalucence had completed little work on the products, and as a result, would not consider the products to add value to Pharmalucence's business when considering the upfront purchase price it would offer to Plaintiffs.

On January 29, 2014, Sun sent Pharmalucence a non-binding proposal. Sun's offer included $60 million upfront and $40 million in deferred earn-out payments. According to the terms of this

offer, the earn-out payments would be based largely on the "[s]uccessful development, filing, approval and launch of 4 new Radiopharm products[.]" PX034.

Plaintiffs had two main issues with the January 29, 2014 proposal. First, Plaintiffs believed that the up-front payment was too low. Second, Plaintiffs were concerned that they would not have enough control over the development of the products that triggered the earn-out payments such that Sun could make them impossible to achieve. Covington communicated these concerns to Sun.

On March 6, 2014, Sun sent Plaintiffs an updated non-binding proposal responding to Plaintiffs' concerns. Sun raised the up-front payment from $60 million to $70 million and added language stating that "if Sun Pharma reprioritizes and files any other product, that product would be considered for the four products qualifying for milestone payment." PX034. On March 14, 2014, Sun and Plaintiffs executed the non-binding proposal. The non-binding proposal contained the provision that would allow Plaintiffs to earn milestone payments upon the filing of four new generic radiopharmaceutical products with the FDA or other appropriate regulatory agency.

On April 8, 2014, following receipt of the non-binding proposal, Plaintiffs and Covington made a management presentation to Sun. Plaintiffs represented through the presentation that, while the radiopharmaceutical market was entering a mature, declining phase, Pharmalucence had the potential to double its radiopharmaceutical business revenue following realization of its four current development projects (the eventual Milestone Products). Plaintiffs also represented that the Billerica Facility would open substantial manufacturing capacity following FDA approval. Suggesting that Sun could take advantage of this open capacity, Plaintiffs represented that Pharmalucence's employees possessed substantial expertise and experience in executing transfers from one facility to another—communicating that Sun would be able to transfer its products to the Billerica Facility.

Part of Sun's rationale for the Acquisition was Pharmalucence's manufacturing capacity in the United States, as well as its R&D capabilities. Prior to the closing of the Acquisition, Sun informed Plaintiffs and Covington that it intended to fill the Billerica Facility's remaining

manufacturing capacity with products from other manufacturing facilities owned by Sun and its affiliated companies. Plaintiffs believed that Pharmalucence had the production capacity to achieve this goal. As part of its diligence efforts, Sun sent one of its employees, Deepak Verma, to visit and evaluate the Billerica Facility and determine whether it would be suitable for the transfer of certain Sun products. Before the Acquisition closed, Sun informed Pharmalucence that it intended to transfer products to the Billerica Facility from other manufacturing facilities owned by Sun and its affiliates. Sun also informed Pharmalucence that it planned to use Pharmalucence as a back-up source for products transferred from the other Sun facilities. Immediately following the Acquisition in July 2014, Sun began discussing potential products to transfer to Pharmalucence but did not discuss the specifics of any potential project.

Sun conducted a due diligence review of Pharmalucence from early 2014 through July 2015. Pharmalucence provided Sun with documents and hosted site visits and inspections of Pharmalucence's business and facilities. Neither party raised an issue with Pharmalucence's capacity to develop or transfer additional products based on the number of development personnel employed by Pharmalucence at the time.

D. The Equity Purchase Agreement

Between March 2014 and May 2014, the parties negotiated the terms of the Equity Purchase Agreement (the "EPA") for the sale of Pharmalucence. On May 15, 2014, Plaintiffs executed the EPA. Plaintiffs agreed to transfer to Sun 100% of the equity in Pharmalucence and a related real estate holding company known as PI Real Estate Ventures, LLC. Plaintiffs received $70 million at closing, less $20 million in debt. Plaintiffs could also receive up to $30 million in contingent, post-closing earn-out payments (the "Milestone Payments") upon the occurrence of certain triggering events (the "Milestones") specified in Schedule 2.4 to the EPA ("Schedule 2.4").

Section 2.4 of the EPA provides:

> **2.4 Earn-Out Payments.** Following the Closing, Buyer shall pay to Sellers the amounts set forth in Schedule 2.4, minus any amounts determined to be due to Buyer pursuant to Section 2.3 or Section 6 and not otherwise paid to Sellers before any such amounts on Schedule 2.4 (if any) become payable pursuant to Schedule 2.4. Except as set forth on Schedule 2.4, to the extent any milestone set forth on Schedule 2.4 is not attained, Buyer shall have no obligation to pay, and Sellers shall have no right to receive any portion of the Earn-Out Payment subject to the attainment of such milestone.

PX001, at 16–17.

Schedule 2.4 identifies four products that, upon the appropriate regulatory filing and regulatory approval within a specified time period, could trigger a total of $25 million in Milestone Payments to Plaintiffs. These products are: (1) tetrofosmin 30 cc vial (generic Myoview); (2) tetrofosmin 10 cc vial (generic Myoview); (3) mertiatide (generic MAG-3); and In-111 pentetreotide (generic Octreoscan) (together, the "Milestone Products").

Schedule 2.4 describes the Milestones and accompanying Milestone Payments as follows:

Milestone Event	**Amount (USD)**
1. Receipt from the FDA of an approval letter in response to filing of a Prior Approval Supplement for the manufacturing site transfer from the Bedford Facility to the Billerica Facility of a Pharmalucence Existing Product.	5 Million
2. Acceptance by FDA of Pharmalucence's ANDA submission for mertiatide (generic MAG-3) by December 31, 2015.	3.125 Million
3. Acceptance by FDA of Pharmalucence's ANDA submission for tetrofosmin, 30 cc vial (generic Myoview) by December 31, 2016.	3.125 Million
4. Acceptance by FDA of the Pharmalucence or its codevelopment partner's ANDA submission for In-111 pentetreotide (generic Octreoscan) by December 31, 2017.	3.125 Million
5. Acceptance by any ex-US regulatory body of the submission of Pharmalucence ANDA or equivalent for tetrofosmin, 10 cc vial (generic Myoview) by June 30, 2017.	3.125 Million
6. Upon receipt of the written and final Regulatory Approval for the MAG-3 product being developed by Pharmalucence in the US from the FDA by December 31, 2018. For the avoidance of doubt, such final, written approval will not be a tentative or conditional approval.	3.125 Million

7. Upon receipt of the written and final Regulatory Approval for the tetrofosmin 30 cc vial product being developed by Pharmalucence in the US from the FDA by December 31, 2018. For the avoidance of doubt, such final, written approval will not be a tentative or conditional approval.	3.125 Million
8. Upon receipt of the written and final Regulatory Approval for the octreoscan product being developed by Pharmalucence in the US from the FDA by December 31, 2019. For the avoidance of doubt, such final, written approval will not be a tentative or conditional approval.	3.125 Million
9. Upon receipt of the written and final Regulatory Approval for the tetrofosmin 10 cc vial product being developed by Pharmalucence in any market outside the U.S. by June 30, 2019. For the avoidance of doubt, such final, written approval will not be a tentative or conditional approval.	3.125 Million

PX002.

Schedule 2.4 also includes a provision the parties have dubbed the "Substitution Provision" for purposes of this litigation. It states:

> Additionally, Buyer, in Buyer's sole discretion, upon prior written notice to Sellers, may reprioritize and substitute for any of the products set forth in the table immediately above. If Buyer substitutes a product, whether that is an existing Buyer product that is transferred into the Facilities or a new product developed in the Facilities, those substituted products qualify for the milestone payments. In the event a product substitution occurs, the milestone timing and milestone payments associated with the product that was replaced ("PL Product") apply to the product that was substituted in its place ("Sun Replacement Product"). For clarification, the first four products that are filed from the facility are subject to the milestones ("Product 1, Product 2, Product 3, and Product 4"). If, for example, the PL Product in the Product 1 slot is substituted by a Sun Replacement Product, the Sun Replacement Product triggers the Product 1 milestone payments (both upon filing and approval) and the PL Product that was originally in the Product 1 slot moves to the Product 2 slot and is therefore subject to the milestone timing and milestone payments associated with the Product 2 slot. For the avoidance of doubt, the milestones set forth above shall be payable based on the first four products submitted for approval (whether PL Products or Sun Replacement Products).

PX002.

The language of the Substitution Provision finalized the understanding reached in the non-binding proposal made in early 2014. The non-binding proposal provided that if Sun re-prioritized and filed any other product, that product would be considered for a milestone payment. Critically, even at this early stage, a product was not considered a substitute merely because it was filed. Instead, Sun needed to take action to reprioritize the product. These same concepts were, in large part, memorialized in the Substitution Provision. Thus, the parties intended that, for a substitution to take place, Sun would need to direct Plaintiffs, in writing, to make an original milestone product a lower priority than a different product. And while the language Sun used to reprioritize a product did not need to explicitly invoke the Substitution Provision, it did need to explicitly place a substituted product ahead of the original milestone product.

Alto understood that, in order for a product to become a Sun Replacement Product, Sun needed to exercise its discretion. Alto also understood that the Substitution Provision required action by Sun and Sun alone—that is to say, actions by Alto or any of the other Plaintiffs were not sufficient to trigger substitution. Finally, the Substitution Provision, in Alto's understanding, required Sun to specify which products where being substituted for Sun Replacement Products.

Plaintiffs further understood the "If, for example . . ." sentence of the Substitution Provision to mean that if Sun substituted a PL Product with a Sun Replacement Product, the original PL Product would move down one slot on the milestone chart and be eligible for a milestone payment subject to the deadline of the next lowest slot. In order to clarify that Plaintiffs could only be paid for a total of four milestone products, the parties included the "For clarification . . ." and "For the avoidance of doubt . . ." clauses. Thus, once a Milestone Product was bumped from the fourth slot, it ceased to be a Milestone Product for which Plaintiffs could claim payment. These clauses, however, were not intended by Plaintiffs to change the way by which substitution occurred. That is to say, substitution still required an exercise of discretion by Sun substituting a specific Sun

Replacement Product for a specific PL Product. As Connolly testified at trial, this language did not change the fact that, if a Milestone Product failed for any reason and Sun did not direct Plaintiffs to replace the product, then Plaintiffs would not be entitled to the relevant Milestone Payment.

Schedule 2.4 next includes a provision the parties have dubbed the "Capacity Provision" for purposes of this litigation. It states:

> In the event that Sun takes any action that materially diminishes the manufacturing and/or development capacity of the Facilities to the extent the ability to file four (4) PL or Sun Replacement Products is materially affected, Buyer shall continue in good faith, the development and filing of remaining PL Products and make any remaining Earn Out Payments on the earlier of (1) when the milestones are achieved within the specified time period, or (2) the deadline specified above as applicable to each milestone, regardless of whether or not milestone has been achieved.

PX002.

Finally, Schedule 2.4 includes a provision the parties have dubbed the "Last Man Standing Provision" for the purposes of this litigation. It states:

> In the event (i) Buyer terminates the employment of the Individual Seller who remains employed with Buyer for the longest period following the Closing without Cause (as defined in the applicable Employment Agreement between Buyer and such employee), (ii) fails to renew the employment of such Individual Seller following the expiration of the term set forth in such Individual Seller's employment agreement with Buyer or (iii) such Individual Seller resigns his employment with Buyer for Good Reason, in either case prior to the earlier of (x) the achievement of the milestones set forth herein, or (y) the expiration of the time in which such milestones may be achieved, then Buyer shall pay the full amount of all potential remaining Earn-Out Payments hereunder, at the time such milestones are achieved, but disregarding any time limitations on the achievement of such milestones.

PX002. As relevant here, the parties intended that clause (ii) of the Last Man Standing Provision would be triggered if, at the end of the last-employed Plaintiff's employment agreement, Sun did not renew that Plaintiff's employment.

Also relevant in this case is the parties' agreed-upon definition of Good Reason for resignation. As defined in the EPA, Good Reason means:

> (i) a material diminution of the duties assigned to an Individual Seller in his Employment Agreement, (ii) a material reduction in an Individual Seller's Base Salary (as defined in his Employment Agreement) . . . ; (relocation of an Individual Seller to an office other than the Billerica Facility; and/or Pharmalucence's material breach of any Employment Agreement.

PX001.

E. Closing of the Acquisition and Subsequent Milestone Payments

The Acquisition closed on July 15, 2014. Sun paid Plaintiffs the $70 million up-front payment in accordance with the terms of the EPA. Sun paid Plaintiffs the first Milestone Payment of $5 million tied to FDA approval of Pharmalucence's Billerica Facility when that payment became due under the terms of the EPA and Schedule 2.4. Sun also, apparently mistakenly, paid the second Milestone Payment tied to mertiatide. Sun has not made Milestone Payments for Milestone Events 3, 4, 5, 6, 7, 8, and 9—totaling $21.875 million.

F. Manufacturing and Product Development at Pharmalucence

1. Manufacturing

i. Capacity

The Bedford Facility measured 13,000 square feet. Manufacturing at the Bedford Facility occurred manually in cleanroom suites. At the time of the Acquisition, all of the products that Pharmalucence sold commercially were produced at the Bedford Facility.

The Billerica Facility was substantially larger than the Bedford Facility at 70,000 square feet. The Billerica Facility had an automated vial formulation and filling line that consisted of a Bosch isolator and an integrated IMA lyophilizer (the "Bosch Line"). An isolator is a partition that separates the formulation and filling line to create an aseptic environment for formulation and filling. A lyophilizer is a freeze dryer used to rapidly freeze pharmaceutical products. Plaintiffs

engaged Timothy Hanrahan, who also testified as an expert in this case, to help Pharmalucence design the Bosch Line to meet state-of-the-art production standards.

As of closing of the Acquisition, however, Pharmalucence was not able to engage in commercial manufacturing activities at the Billerica Facility because it did not have FDA approval. To trigger FDA inspection and approval, Pharmalucence needed to transfer at least one of its products from the Bedford Facility to the Billerica Facility. Until the Billerica Facility obtained approval in April 2016, Pharmalucence was not able to engage in commercial manufacture at that facility.

Because the Billerica Facility was substantially larger than the Bedford Facility, at the time that the Acquisition closed, Pharmalucence was only using between twenty and thirty percent of its manufacturing capacity. Additionally, the Bosch Line had more than enough capacity for the ongoing R&D projects—meaning that Sun could transfer some of its products to the Billerica Facility without impacting the use of the Bosch Line for R&D projects.

ii. Oxygen-Sensitive Manufacturing

Manufacturing and engineering operations at Pharmalucence were managed by Daniel O'Brien. O'Brien oversaw manufacturing of all of Pharmalucence's products at the Bedford and Billerica Facilities. O'Brien worked to determine the requirements for the Bosch Line when it was built and participated in factory acceptance testing of the Bosch Line.

The Bosch Line was located in a production suite which was designed to optimize workflow and environmental controls. Inside the Bosch Line was a train of equipment that performs a series of specialized steps. Glass vials were fed continuously into the machine at one end. A conveyor then moved the vials to a cooling step and then to a filling machine which metered out a precise dosage of drug into the vial. Inert gas purging of the vial before, during and after fill was possible at this stage to protect oxygen-sensitive formulations. Next, the vial moved to a stoppering station and

a stopper was applied and fully seated. The vial would then move to a capping station where an aluminum crimp was applied to affect an aseptic seal. If the vial was to be freeze dried, the vial then traveled by conveyer to the lyophilizer where it was automatically loaded onto shelves for freeze drying. Vials were loaded into the lyophilizer in batches, meaning that vials were lined up in a staging area prior to being loaded. This entire automated process was contained within the barrier isolator system.

Within the isolator, fresh air was blown through a HEPA filter for a high-purity air environment. Thus, although filtered, the composition of air inside the isolator was the same as the air outside the isolator. Because of this, the Bosch Line featured controls for the partial exclusion of oxygen. These control features included (a) Inert gas (e.g., Nitrogen) purging and sparging of the intermediate filling vessel and purging of all associated product path filling lines (purging is the process of displacing the oxygen (air) in an empty vessel with an inert gas while sparging is the process of reducing the dissolved oxygen content in a solution by displacing it with an inert gas); (b) Pre, during and post vial filling gas purge; (c) Formulation /dispensing solution temperature control; (d) Single line vial loading of the filled vial into the lyophilizer. These measures were critical as several of Pharmalucence's existing products were oxygen-sensitive. Despite these features, however, the Bosch Line could only reduce, not eliminate, exposure to oxygen.

Vials loaded into the lyophilizer could be exposed to regular air—that is, air containing oxygen—for several hours. Additionally, it was not uncommon for vials to remain on the line for up to 60 minutes due to unplanned stoppages such as broken vials or mechanical issues. Increasing the speed of the Bosch Line increased the number of unplanned stoppages. Therefore, Pharmalucence estimated, at the time of the events in this case, that the potential amount of time a vial could potentially spend on the Bosch Line was 60–75 minutes. If there were no stoppages, the average time would be 20–25 minutes, but this would not be a realistic estimate given Pharmalucence's experience with the Bosch Line. And the FDA requires a generic pharmaceutical

company to provide test results demonstrating purity for the worst-case scenario, meaning 60 minutes or longer. Plaintiffs, through Hanrahan, argued at trial that, under ideal circumstances, the estimated exposure time for the Bosch Line should have been approximately eight minutes. But this estimate conflicts with the real-world observations presented by Sun's witnesses. Indeed, in reaching his conclusion that a vial should only be exposed for eight minutes, Hanrahan did not visit the Billerica Facility to inspect the Bosch Line and ran no tests to confirm this estimate. The Court discredits Hanrahan's testimony on this point entirely since it is based not on real-world experience with the Bosch Line, but on hypothetical, best-case scenario testing undertaken during installation. Instead, the Court credits the real-world experience of O'Brien, a disinterested witness, over that of Hanrahan, Plaintiffs' retained expert and personal friend.

The original Bosch isolator cost approximately $10 million in 2010, with an additional $1 million in installation costs. It took between 1.5–2 years to install the original Bosch isolator and another 1–1.5 years to obtain FDA approval. A new isolator with inert manufacturing capabilities would cost between $10 and $20 million. The Billerica Facility did not have the space for two isolators, meaning that if Pharmalucence wished to install a new isolator, it would have to remove the original. If Pharmalucence chose to replace its isolator, no products could be manufactured at the Billerica Facility during removal, installation, and approval.

2. Product Development

The product development group at Pharmalucence (the "Development Group") was made up of analytical development scientists and process development scientists. Analytical development scientists developed methods for testing and validating the quality and properties of the products developed and manufactured at Pharmalucence. Process development scientists developed the manufacturing and formulation processes used in manufacturing Pharmalucence's products. The Development Group performed a number of tasks, including new generic product development, site to site product transfers, technical support to implement continuous improvements to

commercialized products, contract services, and support for projects implementing new production technologies.

The Development Group and its manager, Paul Damphousse, reported to Connolly from the 1990s until after the Acquisition. Following the Acquisition, Connolly transferred this responsibility to Alto in order to focus on other projects. Despite this formal change in reporting, Connolly remained apprised of the Development Group's activities and continued to attend some of the group's meetings. The Development Group's manager, Paul Damphousse, joined the company in 1999.

At the time of the Acquisition, Pharmalucence intended to transfer all of its commercially manufactured products from the Bedford Facility to the Billerica Facility for production. Site to site product transfers fell under the purview of the Development Group. Such transfers are known as "technology transfers." A technology transfer is composed of all of the activities associated with moving a previously-approved, FDA-regulated product from one facility to another. It is a personnel-driven activity rather than a manufacturing activity. Pharmalucence personnel had the ability and experience to effect technology transfers in-house.

At the closing of the Acquisition, the Development Group had 12 members. Prior to the closing, Plaintiffs had identified a need for a number of new positions in the production inspection and development areas. Because Plaintiffs were bound to a hiring freeze during the period prior to the consummation of the Acquisition, they were not able to proceed with these hires until after the Acquisition closed. In July 2014, following the closing of the Acquisition, Plaintiffs requested authorization to hire seven additional employees. One position was for an opening in the development group, which existed due to a resignation. The remaining six were for "Inspection & Packaging" and "Formulation & Fill" personnel. Sun approved all of the requested hires. The six Inspection & Packaging and Formulation & Fill personnel were not development scientists and did not increase development capacity.

While Plaintiffs knew from negotiating the Acquisition that Sun was interested in transferring some of its products to the Billerica Facility, as of closing, the Development Group was operating at its maximum capacity. At the time, the Development Group was working on a number of projects, including technology transfers from the Bedford Facility, product development projects, oversight of contract manufacturing activities—in particular a contract for a product known as Definity, preparation for FDA approval of the Billerica Facility, and providing ongoing technical support for the quality control and production groups. While the Development Group had some flexibility, it did not have significant capacity to take on new projects without first reprioritizing some existing projects. At trial, Sun spent a significant amount of time trying to show that Plaintiffs misrepresented Pharmalucence's development capacity during negotiations. But that the Development Group was fully occupied only makes sense. Indeed, while opening the Billerica Facility greatly increased manufacturing capacity, Pharmalucence had not significantly increased its headcount (*i.e.*, its development capacity) prior to the Acquisition. As Damphousse testified at trial, the Development Group was always 100% occupied. And if Pharmalucence was unable to fill the Development Group's time, development employees would be laid off. Sun had conducted diligence prior to the Acquisition and was thus aware of these constraints.

After the Acquisition closed, Alto and Connolly repeatedly informed Sun that the Development Group was fully occupied on its current projects. In particular, both expressed concern that Damphousse was overstretched and asked that Sun approve the hiring of a manager to supervise Damphousse and the Development Group. Rather than hire someone from outside the organization, Sun addressed this issue by assigning an existing Sun executive to oversee Damphousse.

In December 2014, Pharmalucence management determined that it needed two additional employees, one in engineering and one in development. In January 2015, Sun authorized

Pharmalucence to proceed with recruiting for these positions and indicated that it would look to see if it could provide its own internal personnel to fill the positions.

In February 2015, Alto determined that Pharmalucence had sufficient personnel to execute its goals so long as Sun did not require work to begin on product transfers from its facility in Halol, India.

Throughout the time period at issue in this case, Sun repeatedly maintained or enhanced the resources of the Development Group. In April 2015, Sun extended the consulting arrangement with Kathleen Dennis to assist in the development of mertiatide. Dennis worked with Pharmalucence until she decided to terminate her consulting arrangement in July 2015. In Summer 2015, the Development Group requested additional personnel. Sun approved this request. From the time of the Acquisition to the beginning of 2017, Pharmalucence's overall staff grew from 109 to 129.

G. Development of Mertiatide

Mertiatide is a generic for the brand name radiopharmaceutical Technescan MAG3. Mertiatide is a cold kit for the preparation of technetium Tc 99m mertiatide, a diagnostic radiopharmaceutical supplied in a lyophilized powder.

By the time of the Acquisition, Pharmalucence had commenced development work on mertiatide. Pharmalucence had difficulties early on in developing and validating the aerosol test methods for mertiatide. These issues were resolved. Pharmalucence also encountered purity testing failures for mertiatide, and encountered impurities caused by the API received from its API supplier, Dalton Pharma Services ("Dalton"). These issues were also resolved. And Plaintiffs do not contend that the eventual transfers from Sun's facility in Halol, India impacted the development of mertiatide. Instead, throughout the development process, mertiatide was properly resourced and not prioritized below any other product.

On May 2, 2016, Pharmalucence filed an ANDA with the FDA seeking regulatory approval to manufacture mertiatide. On July 8, 2016, the FDA accepted Pharmalucence's mertiatide ANDA for review and on July 12, 2019, the FDA issued regulatory approval of an ANDA for mertiatide. The July 12, 2019 approval would have triggered Milestone 4 if the deadlines for approval did not apply.

H. Development of Pentetreotide

Pentetreotide is a generic for the brand name radiopharmaceutical Octreoscan. Pentetreotide is a kit for the preparation of indium In-111 pentetreotide, a diagnostic radiopharmaceutical. It is supplied as a sterile lyophilized powder.

Pharmalucence had not started any development work on pentetreotide before October 2014. In November 2014, at Plaintiffs' request, Sun agreed to take on development of both the pentetreotide API and final product formulation for pentetreotide at SPIL's facilities in India. The R&D group there had experience with a key component of the product. Meanwhile, another key component of the pentetreotide product was being developed in concert with GE Healthcare.

Pentetreotide experienced several development delays. These delays were caused by difficulties in developing pentetreotide's API and work on transferring pentetreotide methods from India back to the Billerica Facility. Sun was able to resolve those issues. Alto contends that product transfers from Sun's facility in Halol, India caused the development of pentetreotide to be transferred to India. But Plaintiffs offer no evidence that Sun directed or required this transfer. And, likewise, Plaintiffs offered no evidence that the delay caused by the eventual transfer from India back to the Billerica Facility was greater than the time saved in transferring the development to a facility with experienced R&D personnel.

On March 15, 2019, Pharmalucence filed an ANDA with the FDA seeking regulatory approval to manufacture pentetreotide. On March 21, 2019, the FDA accepted the filing of an ANDA for pentetreotide.

Schedule 2.4 sets the deadline for development of pentetreotide as December 31, 2017. Sun has not made a Milestone payment to Plaintiffs associated with the development of pentetreotide. The March 21, 2019 FDA approval would have triggered Milestone 6 if the deadlines were not in place.

I. Development of the Tetrofosmin Products

1. Initial Development Efforts

Tetrofosmin 10 cc (also called "RP-05") and tetrofosmin 30 cc (also called "RP-06") (together, the "Tetrofosmin Products") are generics for different sized vials of the brand name radiopharmaceutical Myoview. The Tetrofosmin Products are myocardial imaging agents. They are supplied as a sterile lyophilized powder. The projected revenue for the Tetrofosmin Products was between two and seven million annually, although Alto estimated the revenues might plateau at three million.

The formulations for the tetrofosmin 10 cc and tetrofosmin 30 cc used the same API, tetrofosmin, and inactive ingredients, except that the tetrofosmin 30 cc formulation included the inactive ingredient ascorbic acid. Ascorbic acid does not increase tetrofosmin's susceptibility to oxidation. Because the products were so similar, the information obtained in the development of tetrofosmin 10 cc could also be used for tetrofosmin 30 cc and vice versa.

As early as 2007, Pharmalucence discussed developing a generic tetrofosmin product. Pharmalucence ultimately did not pursue development at that time and did not perform any material development work.

In May 2013, Pharmalucence opened a dialogue with Cardinal Health ("Cardinal") regarding Cardinal's interest in a co-development contract for tetrofosmin. Pharmalucence had a similar agreement with Cardinal for mertiatide, under which Cardinal had agreed to fund some costs of development. To determine whether Pharmalucence should pursue a co-development agreement with Cardinal, Alto instructed the "best minds" in the Development Group to undertake a feasibility

study for tetrofosmin 10 cc. Five of the twelve employees in the Development Group were assigned to the project. Alto was encouraged by the early results of that feasibility study.

In late September 2013, Pharmalucence and Cardinal tentatively agreed that Pharmalucence would focus its efforts on developing the tetrofosmin 30 cc product exclusively for Cardinal, but that Pharmalucence would also be able to develop the tetrofosmin 10 cc product for non-U.S. markets. Ultimately, however, negotiations with Cardinal stalled over pricing issues. At this time, Alto was not aware, and did not anticipate, any difficulty with developing either Tetrofosmin Product.

By April 2014, the Development Group identified tetrofosmin API as a project concern. As it turned out, tetrofosmin is highly sensitive to oxygen, meaning that it degrades (oxidizes) and becomes less pure in its presence. As early as June 2014—a full month before the closing of the Acquisition—tetrofosmin's oxygen-sensitivity was identified as a concern that could impact production scale. From late June to July 1, 2014, Lynn Sole—the technical lead of the Tetrofosmin Products development projects—conducted experiments to test the stability of tetrofosmin when exposed to oxygen. Sole concluded that the tetrofosmin API was not stable when exposed to oxygen.

Another scientist who worked primarily on the Tetrofosmin Products, Todd Tessier, circulated a draft memorandum on July 31, 2014 summarizing his work to date on the tetrofosmin 30 cc project. On July 31, 2014, Pharmalucence scientist Lisa Lavoie circulated comments to the memorandum but did not change its substantive findings. In his memorandum, Tessier identified numerous concerns with the Tetrofosmin Products, the first of which was a concern that the tetrofosmin formulation was relatively unstable in the presence of oxygen. While Tessier did not determine whether it was feasible or advisable to continue development efforts, he concluded that a significantly purer tetrofosmin API would be necessary for the project to achieve production scale.

As part of his work, Tessier conducted an experiment to assess the rate at which tetrofosmin degrades when exposed to oxygen. Tessier tested the concentration of tetrofosmin in a solution while using a nitrogen sparge—a procedure that removes dissolved oxygen and prevents oxygen from entering a solution. When using the nitrogen sparge, the tetrofosmin did not degrade. Once Tessier removed the sparge, thereby exposing the solution to oxygen, the tetrofosmin degraded quickly. In less than one hour, the tetrofosmin in the solution degraded to less than 95% pure.[2] In less than 30 minutes, the tetrofosmin degraded to less than 98% pure. This was not an acceptable result as Pharmalucence needed the purity level of the tetrofosmin API to be between 98% and 102% in order to use it in manufacturing the final product. This was because further degradation would occur during the production process and it was unlikely that the FDA would accept a purity of less than 95% for the final product.

Nevertheless, Tessier's report did not mean that development of tetrofosmin was not feasible or that the issues he identified could not be solved. These results were not an unexpected part of the development process. And an early result showing less than 5% degradation of API in 30 minutes can support further development of a product.

Because he believed at the time that the issues with developing the Tetrofosmin Products were not insurmountable, Alto met with Damphousse in late August 2014 to discuss further efforts to develop the Tetrofosmin Products. Alto also updated Cardinal in August 2014—as part of the parties' continuing negotiations—that while the Development Group had encountered some issues regarding acquiring sufficiently pure tetrofosmin API, Pharmalucence wanted to complete further work before making any final decisions.

[2] The study "normalized" the purity of the tetrofosmin to judge the rate of degradation. This meant that the starting purity of the tetrofosmin was set as 100% pure, even though the material may have been less pure.

2. Efforts to Secure Sufficiently Pure API

Tetrofosmin API is more oxygen-sensitive than other components of generic cold kits developed by Pharmalucence. Tetrofosmin is what is known as a tertiary phosphine. A tertiary phosphine's molecular structure makes it reasonably to significantly sensitive to oxygen degradation.

In the course of their work, the Development Group determined that it could not continue development experiments unless they obtained sufficiently pure tetrofosmin API. This prevented the Development Group from completing trial batches on the Bosch Line to test processes to limit oxygen exposure. Thus, in order to continue developing the Tetrofosmin Products, Pharmalucence needed to identify a source of tetrofosmin API. Synthesis of APIs is a complicated, multi-step process requiring specialized expertise. The expertise required for tetrofosmin was heightened by the fact that the Development Group determined by September 2014 that a supplier would need to produce tetrofosmin in an oxygen-free environment or otherwise limit oxidation.

There were, generally, four options[3] Pharmalucence could use when seeking API. First, Pharmalucence would place what is called an "off-the-shelf" order. For an off-the-shelf order, a company places an order with a vendor who keeps a supply of the API in stock—much like one might order a shirt from an online retailer. Off-the-shelf API was generally used in early development and was not typically of sufficient purity for Pharmalucence's final development, FDA approval, and manufacturing efforts. The next option for a company seeking API is a so-called "custom synthesis" from a vendor with experience synthesizing the relevant API. This vendor may also supply the API off-the-shelf, but a custom synthesis is made to order—much like ordering a custom suit from an experienced tailor—and is more likely to meet the requisite purity standards. While more expensive than ordering off-the-shelf, the cost of a custom synthesis is relatively low. For example, Dalton offered to supply Pharmalucence with a custom synthesis of tetrofosmin API

[3] At trial, the parties talked past each other regarding the proper nomenclature for the various options for securing API. The Court hopes that this description provides the clarity the parties were unable to supply at trial.

for $5,000. As a third option, for either custom synthesis or off-the-shelf orders, a vendor can attempt to "re-purify" the API to raise its purity to an acceptable level. The final option for acquiring API also involves a custom synthesis—that is, a made to order batch of API—but involves working with a vendor that does not already have a process for synthesizing the particular API to develop such a process and then create a batch of the API. This custom development/synthesis option is much more expensive, with one estimate for Pharmalucence starting at $900,000. It also carries significant risk, as there is no guarantee that the vendor's costly development efforts will result in sufficient quality API.

ABX: In June 2013, Pharmalucence contacted ABX Advanced Biochemical Compounds GmbH ("ABX") in an attempt to obtain tetrofosmin API. ABX informed Pharmalucence that it could not meet the required level of purity for tetrofosmin API. ABX described tetrofosmin as an "ugly" product, prompting Alto to express concerns regarding the feasibility of the tetrofosmin product if sufficiently pure API could not be obtained. Ultimately, Alto determined that the Development Group should focus its API acquisition efforts away from ABX to Dalton.

Dalton: In 2013, Pharmalucence reached out to Dalton as a potential API supplier for the Tetrofosmin Products. Pharmalucence began receiving shipments of tetrofosmin API from Dalton in July 2013. The Development Group experienced difficulties with the tetrofosmin API supplied by Dalton. And in October 2013, Pharmalucence scientist Lisa Lavoie determined that the API was degraded. Pharmalucence received a new lot of tetrofosmin API from Dalton in February 2014. However, stability issues persisted. And by July 2014, the Development Group determined that Dalton's API was not sufficiently pure enough to continue development work. In late September 2014, Dalton offered to make a custom synthesis of tetrofosmin API or to attempt to re-purify an older batch. Damphousse instructed the Development Group to order the re-purified batch. But that batch was ultimately found to be fully degraded. Alto and Dalton discussed searching for a better source of API between August and October 2014, but ultimately Pharmalucence discontinued

efforts to secure tetrofosmin API from Dalton because Dalton could not provide API with the necessary purity to continue development work. In fact, when Dalton offered to make a custom synthesis of tetrofosmin API for $5,000, Alto instructed Damphousse not to pursue the effort as Dalton had not demonstrated that it could be successful.

Sun: In late June 2014, at the suggestion of Sun CEO Kal Sundaram, Alto explored the possibility of Sun making tetrofosmin API at its facilities in India. Alto emailed Sundaram on June 27, 2014 asking whether Sun would be able to synthesize tetrofosmin API to Pharmalucence's specifications. On July 17, 2014, Sun confirmed that tetrofosmin API could be developed at Sun's facility, and that the synthesis would take between eight and ten months. Alto and Sun exchanged further information regarding developing tetrofosmin API on July 28, 2014. Tetrofosmin API was still in development at Sun as of August 19, 2014. But Sun ultimately concluded that it could not produce tetrofosmin API because it was unstable and potentially hazardous to synthesize at its manufacturing facilities. While Sun is an experienced producer of APIs, it is not surprising that it was unable to find success where other experienced API producers also failed.[4]

Alfa: In September and October 2014, Damphousse, Sole, and Tessier attempted to obtain tetrofosmin API from Alfa Chemistry ("Alfa"). Alfa's first batch was degraded and unusable. Alfa offered to send a second batch but found, prior to shipment, that the second batch was also degraded. Alfa then attempted, but failed, to synthesize a custom batch of tetrofosmin API. Finally, Alfa unsuccessfully attempted to re-purify an old batch of tetrofosmin API. Tessier emailed Alfa on

[4] Plaintiffs claim, however, that Sun must have been able to develop tetrofosmin API because Sun's annual report to its shareholders listed that Sun produced 300 APIs and added 25 new APIs annually. Pls.' Opp'n to Def.'s Pretrial Mem., at 11; PX010. But even putting aside the suspect logic in the argument that the ability to produce some APIs means that a company can produce any other API without difficulty, and the proliferation of puffery in reports to shareholders, the fact that Sun could produce other APIs but not tetrofosmin is consistent with the experience of ABX, Alfa, and Dalton, all of which were experienced producers of APIs who could not produce sufficiently pure tetrofosmin API. And Plaintiffs have adduced no evidence suggesting why Sun's efforts should have been more likely to succeed than the other suppliers.

October 21, 2014 that work on the tetrofosmin project was discontinued at that time, halting further efforts.

Albany Molecular Research Inc., PCI Pharma Services, and Chemic Labs, Inc.: Members of the Development Group also obtained quotes to develop tetrofosmin API from Albany Molecular Research Inc., PCI Pharma Services, and Chemic Labs, Inc. These organizations, however, would not agree to develop and sell tetrofosmin API in small enough quantities for development work. Instead, Pharmalucence would have to purchase a quantity that would sustain its commercial manufacturing of the Tetrofosmin Products for an entire year. Additionally, Albany Molecular Research Inc. lacked experience developing tetrofosmin API. Pharmalucence did not pursue API development through these companies.

3. Conclusions Based on Oxygen Sensitivity

The Development Group concluded in September 2014 that it was unlikely to be able to successfully manufacture tetrofosmin products without replacing or significantly renovating the Bosch Line to allow for inert (oxygen free) manufacturing. While Hanrahan claimed that the oxygen controls on the Bosch Line were sufficient to manufacture tetrofosmin, that claim is speculative as Hanrahan conducted no experiments to test this theory. Additionally, his testimony is contradicted by more credible witnesses, such as O'Brien. And it is undisputed that—at the time—the Development Group believed that an oxygen-free environment was required to successfully manufacture the Tetrofosmin Products.

J. The Halol Transfers and Termination of Tetrofosmin Development

1. Tetrofosmin Experiences Technical Issues

Starting in September 2014, efforts to develop the Tetrofosmin Products went downhill. On September 5, 2014, Sole conducted a study that confirmed that the degradation of the tetrofosmin API was due to oxidation. At Alto's direction, Damphousse, Sole, and Tessier, crafted a feasibility determination testing plan for the Tetrofosmin Products. However, the feasibility plan was never

executed because Pharmalucence was not able to obtain sufficiently pure API to conduct the experiments. Plaintiffs claim that the plan was not executed because of the Halol Transfers, but as the Court finds below, the Halol Transfers had not taken place when Alto terminated the Tetrofosmin Products.

Ultimately, the Development Group concluded that developing the Tetrofosmin Products was not feasible and that further testing was unnecessary. Plaintiffs' present claim that further testing was necessary at this point, is belied by the fact that by mid-September 2014, Alto himself was pushing for Sun to "drop" the Tetrofosmin Products. On September 15, 2014, Alto recommended to Sun that Pharmalucence terminate development of the Tetrofosmin Products. Alto noted that the technical difficulties, low price, and commoditization of the Tetrofosmin Products meant that dropping development would be s good strategy for Sun (*i.e.*, it would be a reasonable commercial decision). Alto recommended to Sundaram that Sun replace the Tetrofosmin Products with products made by Mallinckrodt, including a product called Ultratag.

2. Sun Suggests Transferring Certain Products to the Billerica Facility

On September 29, 2014, Amit Kohli, a Sun employee, wrote to Plaintiffs that Sun had identified products to be transferred to Pharmalucence from Sun's facility in Halol, India. Kohli wrote:

> Given the strategic importance of a few vial products, we want to move fast in terms of creating PL as the back up for Halol for those products. Can you please have the team at PL start assessing the feasibility and fast track the transfer process. To begin with lets priortise [sic] the following products[.]

PX101. Those products were zoledronic acid, chlorothiazide, and two vecuronium bromide products (together, the "Halol Transfers"). Plaintiffs now claim that, through this "Halol Directive," Sun reprioritized and replaced the four Milestone Products with the four Halol Transfers. But while the language "fast track the transfer process" is stated as a direction, the email in its entirety is more tentative. Indeed, the first request is to assess the feasibility of transferring the

products at all. The text of the email is not a clear directive. And Plaintiffs' contemporaneous responses demonstrate that they did not believe it to be a directive, instead, they understood the email to open a discussion. On September 30, 2014, Illtifat Hasan, a Sun employee, asked Alto whether any of the identified products appeared on a drug shortage list and what information would be required to initiate the transfers. Alto responded, first writing that none of the products were on the shortage list, and then writing:

> [t]o initiate work, we need to make some decisions. Currently, I have the Development team focused on the transfer of our products from Bedford and development of new products (mertiatide, tetrofosmin, and Octreoscan). Tetrofosmin and Octreoscan are in early stage consideration and could be deferred or cancelled based upon management directive. Decisions should be made that reflect the greatest overall company need. If the decision is made to defer new product development to focus energy in securing [the Halol Transfer Products], we should start an immediate tech transfer process.

PX102. Clearly, the statement that "decisions should be made" and the conditional statement that "*if* the decision is made" show that Alto did not interpret the so-called Halol Directive to direct deferral of development of new products. Alto confirmed this understanding at trial. Indeed, when later asked whether the transfers would require significant Development Group resources, Alto stated:

> Our development team staff this function here. They have the expertise for process transfer. Analytical Assessment could be done by QC Analytical Development. They are at full capacity at the moment and some workload allocation will be necessary to do the transfer. None of this is problematic, it just needs to be managed.

PX102. If the "Halol Directive" had in fact immediately reprioritized the Halol Transfers over the Milestone Products, the allocation of resources would have previously occurred, and Alto would not have responded in this way. Mehta then later responded to Alto that he would discuss priorities with Alto in person when he visited Pharmalucence later that day. While it is not clear what, if any priorities were discussed at this meeting, Plaintiffs acknowledge that they never received specific direction from Sun regarding what specific products should be prioritized—arguing that Sun instead insisted that everything was a high priority.

3. Plaintiffs Unilaterally Terminate Tetrofosmin Development for Ongoing Technical Reasons

Sun never directed Alto to stop development on the Tetrofosmin Products for any reason—much less because of the incoming Halol Transfers. Instead, Alto, in consultation with the other Plaintiffs, determined *himself* that it made sense to pull the plug on tetrofosmin. Ultimately, the decision to terminate the Tetrofosmin Products was made for technical reasons and not because of resource constraints caused by the Halol Transfers. As detailed below, each piece of contemporaneous evidence presented at trial describes the reasons for terminating development of the Tetrofosmin Products as technical issues related to oxidation and the inability to source sufficiently pure tetrofosmin API. On the other hand, Plaintiffs' testimony that the reason for terminating development was the Halol Transfers amounts to no more than an incredible, *post hoc* rationalization developed specifically for this litigation. In other words, Alto lied under oath in this case by asserting that a directive from Sun, rather than a business decision by him, drove the termination of the Tetrofosmin Products. The Court believes that Alto made the decision in good faith, looking out for the interests of Pharmalucence's new owners. But Plaintiffs' narrative that Sun forced the decision is a litigation-fueled falsehood—repeatedly belied by Alto's contemporaneous communications.

On October 2, 2014, Alto directed Damphousse to instruct the Development Group to stop work on the Tetrofosmin Products. Alto wrote:

> Paul, The team has requested an additional $5,000 to have Dalton make more tetrofosmin. However, I haven't heard why this is expected to provide us an adequate chemical. (is the cause of the material degradation understood? Does Dalton assure that the re-make will be successful? Etc. etc.). I recommend that you inform your people that further work on the tetrofosmin project be shelved for the time being. I also recommend that you, [Connolly] and I meet to discuss the priority work that Development is doing. We need to be ready to respond to any request for quick transfers of the Halol based injectables that may be coming near term.

DX122. Alto makes no mention of needing to free up resources for incoming transfers. Instead, he points to ongoing difficulties with development efforts and tells Damphousse to begin to prepare

for transfers that *may* come in the future. In this litigation, Alto attempted to recast his email, stating at trial that "resources were implied in the decision because Halol was about a 50 percent increase in demand on the development team and decisions had to be made. Mr. Sundaram was not engaged to make those decisions. Ultimately, it fell on me." Trial Tr. 110:5–8. But as seen above, no decisions about resources had been made at the time.

Next, on October 6, 2014, Alto informed Cardinal that it should seek an alternative co-development partner for tetrofosmin. Alto wrote:

> With respect to Tetrofosmin, we have had another setback trying to get useful reagent-grade material to allow our process feasibility experiments. To proceed, we must pay for another synthesis and wait. Given the combination of pessimism on the team regarding the feasibility and multiple conflicting demands for resources, we intend to back-burner this program. Cardinal should seek an alternative partner if this remains a priority for you. Should this not be the case and we resurrect the project, I'll let you know.

DX125. In doing so, Alto emphasized the setbacks in obtaining API and—to an outside party—noted the Development Group's pessimism regarding feasibility. While Alto noted conflicting resource demands as well, he understood at the time that Sun had not committed any resources to the Halol Transfers. This understanding is confirmed in the minutes of a Pharmalucence Strategic Planning Committee meeting on October 3, 2014. Regarding the Halol Transfers, the minutes state "Decision needed from Sun management whether to prioritize transfers over further Pharmalucence radiopharmaceutical product development." DX191. And when asked at trial whether, as of October 3, 2014, Sun had given any instruction to shift priorities away from the pipeline products to the Halol transfers, Alto answered that Sun had not.

On October 9, 2014, Alto emailed Sundaram explaining that Alto had informed the Development Group to stop work on tetrofosmin. He wrote:

> I would like to let you know that I have officially informed our Development Group to terminate further development of tetrofosmin. Due to the sensitivity of the active ingredient to oxidation and no good source for its supply, we have been unable to make progress on feasibility studies. From work to date, the technical team has expressed concern about their ability to make this a successful product. I will

> immediately transfer the team from the tetrofosmin work to focus on technical transfer of chlorothiazide, vacuronium bromide and zoledronic acid from Halol.

DX062. In this email, Alto lists the reasons for termination as the sensitivity of tetrofosmin API to oxidation; the inability to secure an acceptable supply of API; and the Development Group's doubts about feasibility of the project. Alto never mentioned the Halol Transfers to Sundaram in discussing the cancelation of tetrofosmin. Nor were Plaintiffs ever given any specific direction to prioritize a transfer product ahead of any of the Milestone Products. In this context, Alto's present claim that the decision to terminate tetrofosmin was actually based on the need to accommodate the Halol transfers lacks credibility.[5]

4. After Plaintiffs Terminate Tetrofosmin, Sun Begins Work on the Halol Transfers

On October 9, 2014, Alto directed Damphousse to form a team to work on technology transfers from the Halol Facility. This was the first task Damphousse undertook regarding the Halol Transfers. At this point, work on the Tetrofosmin Products was suspended and work on pentetreotide had yet to begin.

On October 31, 2014, Pharmalucence and Sun held a kickoff meeting for the Halol Transfers. The meeting identified three products for transfer from the Halol Facility. And, instead of requiring work on all three products at the same time, Sun identified vecuronium bromide as the highest priority for transfer. To open up further development capacity, Sun decided to direct Pharmalucence to continue manufacturing some of its products at the Bedford Facility for the time being. This meant that the Development Group no longer had to spend time on transfers from the Bedford Facility.

[5] Likewise, the Court refuses to credit Alto's testimony that he used the terms "suspend" and "terminate" interchangeably. It is another unfortunate example of Alto's willingness to present transparently false testimony to the Court to advance his position in this litigation.

K. Efforts to Restart Tetrofosmin Development

Months later, in February 2015, Plaintiffs sent Sun a proposed modified Schedule 2.4 that meant to document what Plaintiffs believed were the new milestone products based on Sun's reprioritization. This document, created by Plaintiffs, again states that the reason for terminating the Tetrofosmin Products was related to technical issues and makes no mention of the Halol Transfers.

In April 2015, Plaintiffs learned that Sun believed the failure of the Tetrofosmin Products caused Plaintiffs to forfeit Milestone Payments three, five, seven, and nine. Only after learning of Sun's position did Alto begin to claim that the Tetrofosmin Products were merely backburnered due to Sun's shifting priorities.

Plaintiffs thereafter requested that Sun authorize resumption of work on the Tetrofosmin Products in June 2015. At Connolly's request, Damphousse created a timeline for development showing that the Tetrofosmin Products could still be developed within the time period of the Milestone Events. Damphousse created the document for Connolly, his long-time colleague, as a favor. Damphousse understood that Connolly was requesting it to be used in discussions with Pharmalucence's new management. Connolly framed the request in a way that made it clear to Damphousse that Connolly did not want an accurate timeline to develop tetrofosmin, but, rather, that he should provide a timeline for that product as if it were a normal—relatively easy to develop—product, following a standard timeline template. As requested, the timeline did not address any of the issues regarding API acquisition and oxygen-sensitive manufacturing uncovered in the initial development efforts. As such, Connolly requested a timeline he knew did not address the outstanding issues with developing tetrofosmin. Instead, Connolly requested this document to inform negotiations between Plaintiffs and Sun, possibly as a basis for future litigation. It was not created in the regular course of analyzing a project for development. Thus, the timeline is not a credible analysis of whether it was possible to develop the Tetrofosmin Products within the deadlines set in Schedule 2.4. What's more, Connolly and the other Plaintiffs have always known

that the timeline requested and received was not realistic, but rather a stalking horse. Their efforts now to present it as a realistic timeline are wholly not believable. Plaintiffs also submitted a business plan. Plaintiffs did not, however, propose or identify any resolution of the technical issues that they knew had plagued the earlier efforts to develop the Tetrofosmin Product. Nor was any co-development agreement with Cardinal on the table. As a result, the only change to the cost-benefit analysis for Sun to restart development of tetrofosmin was that a cost-reducing, co-development partner was not available. Sun denied Plaintiffs' request to restart work on the Tetrofosmin Products.

L. Other Project Priorities

Obtaining FDA approval for the Billerica Facility was the top priority for the Development Group until the FDA approved the facility. In January 2015, the Billerica Facility received adverse observations from an FDA inspection conducted in December 2014. In April 2016, Pharmalucence received its first regulatory approval from the FDA to manufacture a commercial product at the Billerica Facility.

In May 2015, Sun requested that the Development Group assist in the transfer of Sun's epoprostenol technology for manufacturing at the Billerica Facility. Damphousse responded by requesting additional staff and that Sun de-prioritize the Halol Transfers relative to epoprostenol. Sun agreed to deprioritize the Halol Transfers in favor of epoprostenol. Additionally, Sun eventually cancelled the transfer of chlorothiazide and zoledronic acid from Halol.

In September 2015, Sun identified the need to accelerate epoprostenol development. Damphousse told Sun that doing so would require either delaying work on mertiatide or vecuronium bromide. Sun chose to delay vecuronium bromide and continue to prioritize work on mertiatide as Pharmalucence intended to submit an ANDA for mertiatide by the end of 2015. Eventually, all of the Halol Transfers were cancelled and never transferred to Pharmalucence.

On November 12, 2013, Pharmalucence entered into a Manufacturing and Supply Agreement with Lantheus Medical Imaging, Inc. ("LMI"). Pursuant to the Manufacturing and Supply Agreement, Pharmalucence agreed to manufacture for LMI's purchase an injectable cardiovascular ultrasound enhancement agent known as Definity. In 2016, after repeated efforts to transfer Definity to the Billerica Facility, Pharmalucence determined that it would not be able to manufacture Definity at the Billerica Facility. In mid-2016, Pharmalucence discontinued work on transferring Definity to the Billerica Facility. Sun terminated the contract for Definity in 2016.

Throughout all of these changes, Sun never provided Plaintiffs with written notice that it was reprioritizing and substituting a specific Sun Replacement Product for a specific Pipeline Product under the Substitution Provision.

M. Plaintiffs' Employment at Pharmalucence

During negotiations for the Acquisition, both Sun and Plaintiffs anticipated that Alto, Waters, and Connolly would continue working at Pharmalucence after the Acquisition. Sun expected that Alto's role and Water's role would be transitioned within one year of the Acquisition. However, Sun recognized that it was possible that either might remain employed for longer than one year. Connolly was given a three-year term of employment that renewed for successive one-year terms unless terminated by either party.

On January 30, 2015, Waters informed Sun and Sundaram, of his intent to resign his employment at Pharmalucence. Water's employment at Pharmalucence terminated on April 30, 2015.

Although Connolly was expected to continue his employment for three years, he submitted a notice of resignation from his employment on March 2, 2015. Connolly withdrew this notice on March 4, 2015. Connolly submitted his second notice of resignation on March 18, 2015. The last day Connolly was employed at Pharmalucence was June 18, 2015.

During negotiations of the employment agreements, Sundaram asked Alto if Alto would consider employment for more than one year. Alto said that he would. Despite this, Alto understood that, absent an extension, he would have no working relationship with Sun after July 15, 2015.

Contemporaneously with the closing of the Acquisition, each Plaintiff entered into an employment agreement with Pharmalucence. Both Alto and Waters agreed to an employment term of one-year, while Connolly agreed to an employment agreement with a three-year term.

Under Alto's employment agreement, his title was Vice President and General Manager of Pharmalucence. During the term of his employment agreement, Alto received a base salary of $300,000. His responsibilities included management of overall operations at Pharmalucence and the Billerica Facility. But the primary purpose of Alto's employment was to "ensure a smooth and efficient transition . . . to [his] successors." Day 1 Trial Tr. 118:23–119:3. Alto was also contractually obligated to take "all reasonable actions to assist [Sun] in achieving on a timely basis each of the milestone events identified in Schedule 2.4." PX005. The contract did not include a right to unilateral renewal by either party. Rather, under the agreement, "[t]he employment of [Alto] by [Pharmalucence] pursuant to this Agreement shall commence on July 15, 2014 . . . and continue for a term not to exceed twelve (12) months unless otherwise terminated by either party . . . ." PX005.

On February 12, 2015, Alto sent an email to a distribution list labeled "staff." In this email, Alto wrote:

> In discussion with Paul [Damphousse] this morning, he expressed concerns regarding a lack of understanding on leadership transition in the coming year. To be clear, I would like to share my intentions. After the sale of the company, I was offered a one year contract to aid integration of the company with Sun Pharma. It expires on July 15, 2015. I will not renew it. In fact, I intend to finish my tenure here on June 30, taking the remaining days as vacation.

DX029. The "staff" distribution list included the Pharmalucence executive team, that is, the heads of the various departments at Pharmalucence.

On February 13, 2015, Alto sent an email to Sundaram. In this email, Alto wrote:

> [W]e lack a succession plan. As you know, Bill is finishing his tenure on April 30 and I will complete my role on July 15 (actually June 30 - I will use vacation in July). Ed's contract term is longer, but in his hands regarding the actual service period. We need to know how you see management structure post June. We are at your disposal to help assure a successful outcome.

DX175. In writing "As you know" Alto was specifically referencing the terms of his employment agreement, not a separate ending date. Accordingly, Alto was not resigning through this email, rather, he was reminding Sun of the terms of his employment agreement.

As of February 12, 2015, Alto did not intend to renew his contract because he did not believe an extension offer was available to him. Alto claimed in an email that, on February 27, 2015, Sundaram told him that Sun did not intend to renew his employment following the expiration of his term. Alto wrote that Mehta is to take the lead going forward and Alto needs to become less visible.

Around the same time, on February 24, 2015, Alto, on behalf of Plaintiffs, sent Sun the updated draft Schedule 2.4 reflecting what Plaintiffs believed were the new Milestone Products based on Sun's reprioritization. In late April 2015, however, Plaintiffs learned that Sun did not believe it had substituted or replaced any Milestone Products. Thus, as Alto's employment was nearing its end, a significant disagreement arose regarding the language of Schedule 2.4.

In May 2015, Sun reiterated its position that it did not wish to renew Alto's employment. But on June 8, 2015, Alto requested that Sun open negotiations to renew his employment. Alto made this request, in part, because Waters and Connolly had already resigned, leaving Alto as the last remaining Seller. Plaintiffs were concerned that Sun would classify Alto's departure at the end of his contract term as a resignation for purposes of the Last Man Standing Provision and wanted Sun to either renew Alto's employment or confirm that they were terminating him. In this, Alto and the other Plaintiffs were driven by what the Court believes to be a misinterpretation of the text of the

Last Man Standing Provision. Alto's actions show that he understood at the time that he did not have a unilateral right to refuse to extend his employment and still trigger the Last Man Standing Provision. Alto also believed that it was important that he remain employed at Pharmalucence in order to oversee work on the remaining Milestone Products and so he could continue to push Sun to restart development of tetrofosmin. Primarily, however, Alto was motivated by the disagreements between Plaintiffs and Sun regarding the milestone events and payments and wanted to extend the Last Man Standing tail.

On June 16, 2015, Sundaram called Alto and denied Alto's request for an extension. On June 22, 2015, as Alto's employment came to an end, Plaintiffs continued to be concerned that Sun would classify Alto's departure in a way that would frustrate the Last Man Standing Provision. Connolly suggested that Alto "be prepared" to continue coming into work after the end of Alto's term unless Alto received a letter stating that his employment was being involuntarily terminated. PX206. The last day Alto performed work at Pharmalucence was June 30, 2015. Alto took the last two weeks of his contract time as vacation after securing approval from Sun, finishing his employment at the end of his contract term.

On July 16, 2015, motivated in part by a desire not to trigger the Last Man Standing Provision, Sun sent Alto an Extended Executive Employment Agreement (the "Proposed Extension Agreement"). The Proposed Extension Agreement provided, in part: (1) that Alto's Executive Employment Agreement ended effective July 15, 2015; (2) that the new employment period would be effective as of July 16, 2015, continuing through December 31, 2015; (3) that Alto would provide advice an oversight for the development of mertiatide and pentetreotide; and (4) that Alto's "services shall be performed primarily at [his] home-based office in Westford, MA, except that [Alto] may report to the [Billerica Facility] one (1) day during each week." PX212. Alto would receive the same base salary.

On July 31, 2015, Alto responded to the Proposed Extension Agreement. Alto objected, in relevant part, to the scope of the duties outlined in the Proposed Extension Agreement, as well as the provision requiring him to work from his home. Based on his concerns at the time that Sun would not honor what he believed were the terms of Schedule 2.4, Alto also requested a provision be added clarifying that the Last Man Standing provision of Schedule 2.4 was triggered—removing any time limitation on the Milestone Events.

On August 3, 2015, Sun's legal counsel sent Alto a response. Sun stated that it did not believe it was necessary or required that it offer Alto his previous title and responsibilities as requested. Sun also stated that it disagreed with Alto's interpretation of Schedule 2.4.

On August 4, 2015, Alto responded with a memorandum to Sundaram. Alto expressed a willingness to continue negotiating the Proposed Extension Agreement, but conditioned further negotiations on resolution of the disagreements over Schedule 2.4. Sundaram casts this as Alto "flatly rejecting Sun's offer and cutting off negotiations over his employment." Sundaram Aff. ¶ 70. But that is not accurate. While Alto's position might have been unacceptable to Sun, he did respond with conditions under which he would have found employment agreeable. Just because Sun did not find his terms acceptable does not mean that Alto cut off negotiations. Similarly, on September 1, 2015, Sun's counsel sent Plaintiffs a letter that included a claim that Alto had not responded to Sun's offer and that this was considered a rejection of the renewal offer. As discussed in the findings of law, Alto was not required to accept a renewal offer. And regardless, Alto did not reject the offer, he countered with terms Sun was not willing to accept.

Alto and Sun attempted to restart negotiations over Alto's employment in mid-September 2015. Ultimately, negotiations failed due to their disagreements regarding Schedule 2.4. The Proposed Extension Agreement was never executed. And Alto never resumed employment with Pharmalucence or Sun.

N. Objective Industry Standards

At trial, Sun submitted expert testimony regarding the objective standard by which commercial reasonability should be judged in the pharmaceutical industry. Dr. Mark Robbins, an industry expert with over 40 years' experience—including evaluating and selecting development projects—testified that decision-making on development projects involves an assessment of the following factors:

- Overall commercial opportunity to assess the potential return on investment;
- The opportunity costs associated with the development of a particular product;
- The strategic fit with the company;
- The risks associated with development, including the overall difficulty of the project and the likelihood for success;
- The technology fit with facilities, equipment, and expertise of the development staff;
- The cost of development including the required capital investment; and
- Intellectual property considerations.

Robbins Aff. ¶ 25. Robbins further testified that, when assessing whether to replace or modify production equipment, companies generally consider the following:

- The feasibility and cost of modifying the equipment;
- The likelihood of success in being able to modify the equipment to meet the design requirements following the modifications;
- The time required to modify the equipment;
- The downtime on the equipment for while it is out of service and the impact on other projects and commercial production;
- The regulatory and quality impact of the modifications on the commercial use of the equipment including validation requirements and functionality impact;
- The overall capacity of the equipment and cost implications on all products manufactured on the equipment.

Robbins Aff. ¶ 45.

In applying industry standards, Robbins explained that it is both preferred and common industry practice to obtain API from companies that already have the substance available. This is

because retaining a supplier to engage in custom synthesis for a product it does not already make can require paying that supplier to develop a manufacturing process, conduct stability studies, and validate the process—all with the risk that the supplier may not ultimately be able to produce a product with the requisite purity. While Hanrahan, testified that requests for custom synthesis are common in the industry, Robbins specifically addressed custom synthesis where a supplier has no experience making a product. This distinction is critical where, as here, Pharmalucence considered engaging API suppliers with no experience in developing tetrofosmin API. Critically too, Hanrahan did not assess whether Pharmalucence could have successfully sourced API from the inexperienced suppliers.

Robbins next opined that a company would not typically install a new fill line in a situation such as this. He testified that it generally takes two years to identify, obtain, and install a new isolator once a company decides to replace its equipment. And that, subsequent to installation, a company needs to obtain FDA approval, which can take three years or more. According to Robbins, companies generally consider the cost of investing in new equipment relative to the potential revenues from the product using that equipment.

Robbins's analysis stands without counterpoint because Plaintiffs offered no expert testimony regarding objective standards for commercial reasonability in the pharmaceutical industry. Instead, Plaintiffs' expert, Timothy Hanrahan, offered a scientific feasibility opinion and explicitly disclaimed any opinion that considered commercial or business factors.[6] While not directly relevant

[6] Indeed, the entire premise of Hanrahan's opinion is somewhat confusing. It is undisputedly feasible to develop and manufacture tetrofosmin. Indeed, as pointed out by Plaintiffs and Hanrahan, GE has been manufacturing the brand name tetrofosmin products since the mid-1990s. The problem faced by Plaintiffs is that Pharmalucence was unable to replicate GE's success. And the question for the Court here is not whether doing so was possible, but whether a similarly situated pharmaceutical company would have continued in the face of: (1) the costly, seemingly Sisyphean task of ordering tetrofosmin API only to have it arrive degraded and unusable; and (2) the risk that, after expending time and effort on securing the API, testing might confirm that the production facility lacked the necessary equipment for successful development. By Plaintiffs' logic, it would have been feasible for Sears to launch a successful online marketplace because Amazon existed. (It did not.) And it would be feasible for every car company to manufacture a profitable, high mileage all-electric car, because Tesla existed. (They have not—yet.) That scientific feasibility and commercial feasibility are profoundly different inquiries is a concept that Plaintiffs seem to disregard.

to commercial reasonability, scientific feasibility could shed light on the credibility of Sun's claims that it did not believe it could successfully develop tetrofosmin at the time it refused to restart development. Here, however, Hanrahan's scientific feasibility opinion is of little use. Hanrahan listed three products that Pharmalucence successfully developed to support his conclusion that Pharmalucence could have developed the Tetrofosmin Products. But Hanrahan undertook no analysis comparing the oxygen sensitivity of these products with tetrofosmin and otherwise undertook no analysis of the chemistry of these products. Likewise, Hanrahan undertook no analysis of the chemistry of tetrofosmin to determine whether it in fact required an inert production environment. Finally, while Hanrahan pointed to GE's success as support for his conclusions, he admitted on cross examination to have no insight into GE's methods for securing tetrofosmin API or GE's production methods for its tetrofosmin products. One can imagine a world in which Hanrahan testified that developing the Tetrofosmin Products was not only feasible, but required only relatively similar efforts to those for the development of Pharmalucence's other products. In such a case, claims that Sun believed at the time that further development efforts were hopeless would be much less credible. Unfortunately for Plaintiffs, Hanrahan undertook no such analysis. And, accordingly, his testimony does little if anything to impeach the credibility of Sun's analysis regarding the unlikely success of the Tetrofosmin Products.

IV. CONCLUSIONS OF LAW

Plaintiffs presented five claims at trial.[7] Count II seeks a declaratory judgement that Sun triggered the Last Man Standing Provision, eliminating the deadlines for the Milestones. Count III claims that Sun breached Schedule 2.4 in failing to pay the Milestone Payments for mertiatide and pentetreotide (Milestones four and six). Counts IV and V claim that Sun breached the Capacity Provision and Commercially Reasonable Efforts Provision respectively. Finally, Count VI claims

[7] This Court previously dismissed Count I following Sun's motion to dismiss. *See Alto v. Sun Pharm. Indus., Inc.*, 2020 WL 2086220, at *11 (S.D.N.Y. Apr. 29, 2020).

that Sun breached the implied covenant of good faith and fair dealing by declining to substitute a product for the Tetrofosmin Products or restart the Tetrofosmin Products' development.

A. The Substitution Provision

A threshold issue in this case involves the effect of the Substitution Provision and whether Sun substituted any of the original Milestone Products with Sun Replacement Products. As described in detail below, the language of the EPA and Schedule 2.4 clearly and unambiguously requires specific written notice substituting or replacing a PL Product with a Sun Replacement Product. Because Sun indisputably did not give such notice, the original Milestone Products remained in place.

Plaintiffs claim that the text of the Substitution Provision is unambiguous and entitled Plaintiffs to the Milestone Payments for the first four products filed and approved from the Billerica Facility, regardless of whether Sun specifically substituted or reprioritized any Sun Replacement Product for an original Milestone Product. Pls.' Pretrial Mem., at 1. Under this theory, Sun's purportedly ambiguous, shifting project priorities are irrelevant, and the parties need only look to which products were filed from the Billerica Facility to determine which products counted for the Milestones. Sun counters that the unambiguous language of the Substitution Provision required written notice from Sun substituting or reprioritizing a specific Milestone Product with a Sun Replacement Product. Under Sun's theory, because it never specifically substituted or replaced any of the original Milestone Products with another product, the original Milestone Products remain.

Section 8.9 of the EPA states that the agreement will be governed by New York law. DX200. "A contract must be construed to effectuate the intent of the parties." *MBIA Ins. Corp. v. Patriarch Partners VIII, LLC*, 842 F. Supp. 2d 682, 704 (S.D.N.Y. 2012) ("*MBIA I*") (citing *Hunt Ltd. v. Lifschultz Fast Freight, Inc.*, 889 F.2d 1274, 1277 (2d Cir. 1989). "[T]he best evidence of the parties' intent is what they expressed in their written contract." *Benihana of Tokyo, LLC v. Angelo, Gordon & Co., L.P.*, 259 F. Supp. 3d 16, 33 (S.D.N.Y. 2017), *aff'd*, 712 F. App'x 85 (2d Cir. 2018).

"The first step in interpreting a contract is to determine whether its language is ambiguous." *United States v. Prevezon Holdings, Ltd.*, 289 F. Supp. 3d 446, 451 (S.D.N.Y. 2018) (citing *Lockheed Martin Corp. v. Retail Holdings, N.V.*, 639 F.3d 63, 69 (2d Cir. 2011)). "Ambiguity must be determined on the face of the contract; extrinsic evidence may not be introduced in an attempt to create ambiguity." *Charron v. Sallyport Global Holdings, Inc.*, 2014 WL 7336463, at *16 (S.D.N.Y. Dec. 24, 2014) (quoting *Lockheed Martin*, 639 F.3d at 69). "The threshold question of whether a contract is ambiguous is an issue of law for this Court to decide." *Prevezon*, 289 F. Supp. 3d at 451 (citations omitted). A contract is unambiguous if its "language has a definite and precise meaning . . . concerning which there is no reasonable basis for a difference of opinion." *Chesapeake Energy Corp. v. Bank of N.Y. Mellon Trust Co., N.A.*, 773 F.3d 110, 114 (2d Cir. 2014) (quotation marks omitted). Conversely, a contract is ambiguous if a "reasonably intelligent person viewing the contract objectively could interpret the language in more than one way." *Topps Co., Inc. v. Cadbury Stani S.A.I.C.*, 526 F.3d 63, 68 (2d Cir. 2008).

"If the contract is unambiguous . . . , the court is not to consider any extrinsic evidence as to the parties' intentions." *JA Apparel Corp. v. Abboud*, 568 F.3d 390, 397 (2d Cir. 2009) (citations omitted). "[A] written agreement that is complete, clear, and unambiguous on its face must be [interpreted] according to the plain meaning of its terms." *Law Debenture Tr. Co. of New York v. Maverick Tube Corp.*, 595 F.3d 458, 467 (2d Cir. 2010) (quoting *Greenfield v. Philles Records, Inc.*, 780 N.E.2d 166, 170 (N.Y. 2002)). In interpreting a contract, courts "examine the entire contract and consider the relation of the parties and the circumstances under which it was executed. Particular words should be considered, not as if isolated from the context, but in the light of the obligation as a whole and the intention of the parties as manifested thereby." *MBIA I*, 842 F. Supp. 2d at 704 (quoting *Kass v Kass*, 696 N.E.2d 174, 181 (N.Y. 1998)).

Here, the language of the EPA and Schedule 2.4 clearly and unambiguously requires specific written notice substituting or replacing a PL Product with a Sun Replacement Product. The

language giving Sun "sole discretion" to make a substitution upon "prior written notice," along with the structure of the Milestones requires this result.

Plaintiffs' contrary reading would render superfluous everything in the Substitution Provision except the two sentences added for "clarification" and "avoidance of doubt," which is certainly a dubious method of contract interpretation. *See LaSalle Bank Nat. Ass'n v. Nomura Asset Cap. Corp.*, 424 F.3d 195, 206 (2d Cir. 2005) ("[A]n interpretation of a contract that has the effect of rendering at least one clause superfluous or meaningless . . . is not preferred and will be avoided if possible." (quotation marks omitted)). Further, under Plaintiffs' reading, it would be difficult, if not impossible, to determine which milestone event applied to which product. Interpreting the provision to cause a confusing or absurd result is also not best practices in contract interpretation. *Homeward Residential, Inc. v. Sand Canyon Corp.*, 298 F.R.D. 116, 129 (S.D.N.Y. 2014) ("[A] court must avoid any interpretation that would be 'absurd, commercially unreasonable, or contrary to the reasonable expectations of the parties.'" (citation omitted)).

Regardless, Plaintiffs' reading conflicts with the text and structure of the agreement. First, the text of the so-called "first four out" language does nothing to alter the process for substituting a product. That language is explicitly meant to clarify the effect of, not modify the procedure for, substituting a product. Under Plaintiffs' reading, however, the clarification would swallow the rule and create a different method for substitution.

Second, the text describing the Milestone Payments states "to the extent any milestone set forth on Schedule 2.4 is not attained, Buyer shall have no obligation to pay, and Sellers shall have no right to receive any portion of the Earn-Out Payment subject to the attainment of such milestone." EPA § 2.4. Thus, if Plaintiffs failed to develop the Milestone Products for any reason, they would not be entitled to the Milestone Payments. But if the Milestones automatically apply to the first four products filed from the Billerica Facility, then Plaintiffs' failure to develop the Milestone Products would have no effect so long as some product was filed from the facility within the Milestone

deadlines. The problems with such a reading are further compounded if the Last Man Standing Provision is triggered, removing any time constraints from the Milestone Payments.

Third, and similarly, Plaintiffs' interpretation reads out Sun's "sole discretion" to substitute or replace a product. If all that matters is the "first four" language, then substitution is automatic, not discretionary. If substitution were automatic, then, as here, Plaintiffs could unilaterally cancel a development project and effectively force Sun into substituting in a new product. Not only would this allow Plaintiffs to profit despite the failure of their own efforts, it would effectively give *either* party unilateral discretion to substitute a product. Both of these scenarios expressly contradict the text of the agreements.

Finally, the defined terms "PL Product" and "Sun Replacement Product" both rely on Sun's exercise of its discretion. "PL Product" refers to "the product that was replaced" in the event of a product substitution. PX002. And "Sun Replacement Product" refers to the "product that was substituted." PX002. Both defined terms specifically refer to substitutions implemented as a result of the exercise of Sun's sole discretion and upon prior written notice. PX002. Therefore, if a product was filed from the Billerica Facility, but was not substituted by Sun or replaced by a product substituted by Sun, it could not be a PL Product or a Sun Replacement Product. And as the contract only allows substitution by Sun Replacement Products for PL Products, the non-substituted, first-filed product would not qualify for a Milestone. The defined terms used in the language upon which Plaintiffs rely incorporates the requirement that Sun has expressly substituted the product. Plaintiffs' proposed construction of the contract does not give effect to the utilization of the defined terms in the text.

The parties agree that Sun never gave written notice specifically substituting or replacing a PL Product with a Sun Replacement Product. Accordingly, the original Milestone Products remained in place.

B. Count II: Declaratory Judgement

Plaintiffs seek a declaratory judgement that Sun triggered the Last Man Standing Provision when it failed to renew Alto's employment. Am. Compl. ¶ 7. "In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a).

The Last Man Standing Provision removes the deadlines for the Milestones if Sun terminates the last remaining Plaintiff without cause, fails to renew the last remaining Plaintiffs' employment, or if the last remaining Plaintiff resigns for Good Reason as defined in the EPA. The parties agree that Alto was the "Individual Seller who remains employed with Buyer for the longest period following the Closing," but disagree over whether Alto resigned and/or Sun failed to renew[8] his employment.

The Last Man Standing Provision was almost certainly drafted with Connolly's three-year term of employment in mind. In Connolly's employment agreement, his initial term would be extended for successive one-year periods unless either the company or Connolly provided 90 days' written notice not to extend. In this context then, "fails to renew" was intended to require an affirmative action to end the automatic extension of Connolly's employment. Connolly's early resignation disrupted this structure, as Alto's Employment Agreement contains no such provision. Still, the language of the Substitution Provision applies in the same way with respect to Alto's

[8] As written, there is a glitch in the Last Man Standing Provision. The provision reads: "In the event (i) Buyer terminates the employment of the Individual Seller who remains employed with Buyer for the longest period following the Closing without Cause . . . (ii) fails to renew the employment of such Individual Seller following the expiration of the term set forth in such Individual Seller's employment agreement with Buyer or (iii) such Individual Seller resigns his employment with Buyer for Good Reason." PX002. But clause (ii) is missing a noun, making it somewhat unclear who it is that is supposed to renew the Individual Seller's employment. No party raised this as an issue—proceeding throughout this litigation assuming that obligation was on Sun. That makes sense under the structure of the agreement. Here, the word "fails" connotes a negative consequence to failure to renew. And triggering the Last Man Standing Provision would be negative to the Buyer, not the Sellers. Thus, while somewhat clunky, in the context of the entire provision, the first two clauses should, as the parties presume, refer to actions taken by the Buyer (Sun) while the final clause refers to an action by the Individual Seller (Alto). This reading is confirmed by the testimony by Fisher and Sundaram, who both believed that the Last Man Standing Provision required Sun to renew Alto's employment. To the extent that the provision would be rendered ambiguous as a result of the missing noun, the extrinsic evidence supports the conclusion that, as the parties asserted throughout this case, the obligation rested with "Buyer."

employment even if it does not fit perfectly given the difference in the structure of his employment agreement. And if Alto's employment was not renewed, then the time limitations for the Milestone Payments would be removed.

What was required to "renew" Alto's employment was not clearly understood by the parties as they maneuvered around the impact of Alto's departure from the company and its effect on the Last Man Standing Provision. But the text of the language itself is clear. Under any common sense meaning of the term, Sun failed to "renew" Alto's employment.

First, "renew" may be defined as "to restore to existence." Merriam-Webster, https://www.merriam-webster.com/dictionary/renew (last visited Oct. 12, 2021). Under this definition, renewal would require more than a mere offer, it would require actual restoration. Alto's employment ended with his contract term and never resumed. Thus, Sun would be required to "restore [Alto's employment] to existence" and in failing to do so, failed to renew Alto's employment.

Second, "renew" may be defined as "to . . . obtain an extension of or on." *Id.* But Sun would fail under this definition for the same reasons it would fail under the "restore to existence" definition—namely that it never obtained an extension of Alto's employment.

Third, "renew" may be defined as "to grant . . . an extension of or on." *Id.* Sun did not successfully "renew" Alto's employment under this meaning of the term. Sun did not grant Alto an extension of his prior employment. It offered him a new job, starting the day after the end of his prior term of employment. The new position differed substantially in all regards—substantially limiting the scope of his responsibility, and even his access to the company's facilities. Because Sun offered Alto a substantially different job beginning the day after his prior term expired, it did not grant him an extension of his employment. Sun's internal human resources documentation accurately reflected this fact when they described the circumstances of his departure with the notation "position elimination end of contract."

Finally, Sun argued in its pretrial memorandum that "renewal" should be defined as the "re-creation of a legal relationship or the replacement of an old contract with a new contract, as opposed to the mere extension of a previous relationship or contract." Renewal, *Black's Law Dictionary* (11th ed. 2019) (cited in Def.'s Pretrial Mem., at 40). But not even Sun's selected definition allows for a mere offer to effect renewal. The phrases "re-creation of a legal relationship" and "replacement of an old contract" both require the implementation of a final agreement, not merely the delivery of an offer. Accordingly, Sun did not renew Alto's employment. Ultimately, Sun's proposed interpretation of the agreement is not faithful to its text. Sun asks the Court to rewrite the contract and to construe it as if it read Buyer "fails to *offer to* renew the employment of such Seller," rather than its actual text—"fails to renew the employment . . . ." The Court cannot do so. The Court must, instead, be guided by the text, which is clear.[9]

Therefore, under the terms of the Last Man Standing Provision, if Sun did not make Alto an offer Alto was willing to accept, Alto had the right to walk away at the end of his contact term without concern that the projects he left behind would not meet the Milestone deadlines. Alto's employment agreement did not contain any provisions by which he or Sun could unilaterally renew his employment. And the plain language of the contract required that Sun renew Alto's employment and the condition failed if his employment did not continue.

Separately, even if "renew" only required Sun to offer Alto further employment, the offer made by Sun would have allowed Alto to resign for Good Reason under the terms of the EPA. This is because: (1) it materially altered Alto's responsibilities in that it would limit his work to

[9] Although the text is clear and the Court need not rely on extrinsic evidence to interpret it, as dicta the Court observes that this interpretation of the contract is consistent with the extrinsic evidence presented at trial regarding the intentions of the parties at the time of negotiation of this provision. While the witnesses who testified on the topic disagreed about whether the terms of the renewed employment had to be identical, the Court finds that both parties' expectation was that the provision required that the parties successfully retain the continued employment of the Seller at issue. As noted above, the Court finds that Alto did not understand this feature of the agreement at least during the early stages of his maneuvers to extend his employment at the company, but that evidence of his understanding of the meaning of the contract years after its formation does not displace the Court's conclusion that the intention of the parties at the time of contracting was consistent with the Court's interpretation of the text.

mertiatide and pentetreotide—not allowing him to work on the rest of the Milestones, including any potential Sun Replacement Product; and (2) it did not allow Alto to work from the Billerica Facility but required him to work substantially from his home office. Thus, even if "renew" required only that Sun offer continued employment, the terms offered were insufficient to "renew" Alto's employment.

Thus, Sun's defense must rise or fall on whether Alto resigned in February 2015. "'Resignation' is defined as '[t]he act . . . of surrendering or relinquishing an office.'" *Airgas Specialty Gases Inc. v. Dumar*, 466 F. App'x 41, 43 (2d Cir. 2012). Alto did neither. Rather, Alto informed the Pharmalucence staff of the impending expiration of his employment agreement and his then-intention not to renew. Remember that the text of Alto's employment agreement provided a specific term for the duration of his employment: "the employment of [Alto] . . . pursuant to this Agreement shall commence on July 15, 2014 . . . and continue for a term not to exceed twelve (12) months . . . ." PX005. Under the terms of the agreement, Alto's employment with the company automatically expired at the end of the term. He informed Sundaram of that fact. Alto's statement to Sundaram that "as you know . . . I will complete my role on July 15" was not a reference to a resignation, but a reference to the one-year term of Alto's employment agreement. Alto then continued to work at Pharmalucence through the end of his contract term. Sun's own internal human resources documentation stated that the reason for separation was "position elimination end of contract." PX241a. Thus, Alto did not "surrender" or "relinquish" his position until his term expired. And, accordingly, he did not resign.

Because Alto did not resign and because Alto's employment was not renewed as of the expiration of his employment agreement, the Last Man Standing Provision was triggered, and the Milestone deadlines ceased to have effect.

C. Count III: Milestone Payments for Mertiatide and Pentetreotide

Schedule 2.4 of the EPA provides that Plaintiffs are entitled to a Milestone Payment if the FDA accepted Pharmalucence's application to market pentetreotide by December 31, 2017 (Milestone four). Likewise, Schedule 2.4 provides that Plaintiffs are entitled to a Milestone Payment if the FDA approved Pharmalucence's application to market mertiatide by December 31, 2018 (Milestone six). The parties agree that the FDA accepted both mertiatide applications, albeit after the deadlines listed in Schedule 2.4. As found in Count II, the Milestone deadlines no longer apply. Accordingly, Plaintiffs were entitled to the payments for Milestones four and six.

D. Count IV: Breach of the Capacity Provision

Plaintiffs next claim that Sun breached the Capacity Provision of Schedule 2.4 by transferring the manufacturing and production of certain products from Sun's Halol Facility to the Billerica Facility. In particular, Plaintiffs argue that the Halol Transfers materially diminished the manufacturing and/or development capacity at Pharmalucence, affecting the ability to file four PL or Sun Replacement Products, including both tetrofosmin products. "Under New York law, a breach of contract claim requires proof of (1) an agreement, (2) adequate performance by the plaintiff, (3) breach by the defendant, and (4) damages." *Fischer & Mandell, LLP v. Citibank, N.A.*, 632 F.3d 793, 799 (2d Cir. 2011). The party bringing the breach of contract claim has the burden of proving each of these elements by a preponderance of the evidence. *See Prime Mover Cap. Partners, L.P. v. Elixir Gaming Techs., Inc.*, 793 F. Supp. 2d 651, 674 (S.D.N.Y. 2011).

As to the tetrofosmin products, Plaintiffs have failed to prove that the Halol Transfers affected their ability to file the two tetrofosmin products. Instead, the evidence at trial established that Alto terminated development efforts independent of any directive or pressure from Sun. Indeed, while the Halol Transfers were discussed, Sun specifically told Alto to hold off on deprioritizing work on the Tetrofosmin Products until priorities were set. The evidence at trial showed that Alto terminated work on the Tetrofosmin Products because of the ongoing technical

difficulties and inability to source sufficiently pure API. This occurred prior to any work by Pharmalucence on the Halol Transfers. As a result, Sun's actions could not have materially affected capacity in a way that prevented further development of the Tetrofosmin Products.

As to mertiatide, Plaintiffs acknowledge that development of this product was fully resourced at all times. As such, the delayed development of mertiatide is not a basis to trigger the Capacity Provision.

As to pentetreotide, Plaintiffs acknowledge that they requested that Sun move development from Billerica to India. Thus, any delays in transferring the product back to the Billerica Facility are properly attributed to the actions of Plaintiffs. The Capacity Provision specifies that if "*Sun* takes any action that materially diminishes the manufacturing and/or development capacity," the Capacity provision is triggered. Schedule 2.4 (emphasis added). As Sun did not take the action that caused the delay, the development of pentetreotide is not a basis to trigger the Capacity Provision.

Regardless, for both mertiatide and pentetreotide, Pharmalucence was eventually able to file these products. And because the Milestone deadlines were no longer in effect following the end of Alto's employment term (*see* Count II), Plaintiffs fail to show that Pharmalucence's ability to file these products was diminished.

E. Count V: Breach of Commercially Reasonable Efforts Clause

Section 5.2 of the EPA states that "[e]ach of the parties hereto shall use commercially reasonable efforts to take all action and to do all things necessary, proper, or advisable in order to consummate and made effective the transactions contemplated by this Agreement." DX200 § 5.2. Plaintiffs claim that Sun violated this provision by failing to reinstate development to tetrofosmin upon Plaintiffs request in 2015 and failing to recognize any Sun Replacement Products under the Substitution Provision.

1. Scope of Commercially Reasonable Efforts Clause

As an initial matter, Plaintiffs argue that this provision required Sun to not only use commercially reasonable efforts in developing the PL Products and any Sun Replacement Products, but actually *required* Sun to designate Sun Replacement Products under certain circumstances. According to Plaintiffs, commercially reasonable efforts is not only limited to developing products but includes efforts to secure for Plaintiffs the Milestone Payments. In support of this argument, Plaintiffs cite to this Court's decision on Sun's motion to dismiss. There, the Court found that "[b]y its plain terms, Section 5.2 refers to 'the transactions contemplated by this Agreement[.]' The *Milestone Payments* are such a transaction." *Alto v. Sun Pharm. Indus., Inc.,* 2020 WL 2086220, at *9 (S.D.N.Y. Apr. 29, 2020) (emphasis added) (citation omitted).

Ultimately, this argument proves too much. And the context, structure, and text of the EPA and Schedule 2.4 foreclose this particular interpretation of the contract.

First, Plaintiffs' reading is circular. The Milestone Payments are contingent upon the development of specific products. If commercially reasonable efforts were tied only to the Milestone Payments, then a commercially reasonable effort might be simply to pay Plaintiffs the Milestone Payments. Sun would, correctly, argue that this is not commercially reasonable to simply pay Plaintiffs the Milestone Payments unless Plaintiffs triggered the Milestone Events (i.e. developed the specific products). But this does not necessarily mean that Sun is required to make additional products available to Plaintiffs once Plaintiffs have determined a product is not workable.

Second, the parties agree—and it is in fact the law—that "[a] contractual requirement to act in a commercially reasonable matter does not require a party to act against its own business interests, which it has a legal privilege to protect." *MBIA Ins. Corp. v. Patriarch Partners VIII, LLC*, 950 F. Supp. 2d 568, 618 (S.D.N.Y. 2013) ("*MBIA II*") (quotation marks omitted); *see also Holland Loader Co.,* 313 F. Supp. 3d at 473. Under Plaintiffs reading, however, if Plaintiffs were unable to make progress on a Milestone Product, Sun would be required to expend its resources to search out,

select, and replace the Product with a product Plaintiffs would—hopefully—be able to develop in time. This reading would essentially require Sun to insure Plaintiffs against their failure to develop Milestone Products. But it is not in Sun's commercial interest to pick up Plaintiffs every time they fall. Again, the contingent structure of the Milestone Payments suggests that the parties contemplated that Plaintiffs might fail to develop a product and that Sun would not designate a replacement.

Finally, the Substitution Provision, which provides the mechanism by which Sun could replace a failed product under Plaintiffs' reading, gives Sun the sole discretion to substitute or replace a PL Product with a Sun Replacement Product. But if the general commercial reasonableness provision required Sun to substitute or replace a product because Plaintiffs determined development of a PL Product was not feasible, then the substitution or replacement would no longer be in Sun's sole discretion. Under New York law, "[w]here there is an inconsistency between a specific provision and a general provision of a contract, the specific provision controls." *Oldcastle Precast, Inc. v. U.S. Fid. & Guar. Co.*, 458 F. Supp. 2d 131, 142 (S.D.N.Y. 2006) (quoting *Aguirre v. City of New York*, 625 N.Y.S.2d 597 (N.Y. App. Div. 2d Dep't 1995). Because extending the general commercial reasonableness provision to require Sun to substitute or replace Milestone Products would conflict with a specific provision of the contract, the specific provision must control. Accordingly, the commercial reasonableness provision did not require Sun to replace or substitute any Milestone Products.

Thus, the question remains whether Sun undertook commercially reasonable efforts in the development of the Milestone Products. It did.

2. Standard For Commercially Reasonable Efforts

"There is no settled or universally accepted definition of the term 'commercially reasonable efforts.'" *Citri–Lite Co. v. Cott Beverages, Inc.*, 721 F. Supp. 2d 912, 926 (E.D. Cal. 2010). "The few cases addressing 'commercially reasonable efforts' clauses under New York law, however, have held

that such a clause is to be analyzed objectively, not subjectively." *Holland Loader*, 313 F. Supp. 3d at 471 (citing cases). But under no circumstances is a party required to act against its own business interests. *Id.* at 472 (citing *MBIA II*, 950 F. Supp. 2d at 618).

When the term "commercially reasonable efforts" is not defined by the contract, a party seeking to enforce the provision must establish the objective standard by which the breaching party's efforts are to be judged, in the context of the particular industry. *Holland Loader*, 313 F. Supp. 3d at 472; *see also Sekisui Am. Corp. v. Hart*, 15 F. Supp. 3d 359, 381 (S.D.N.Y. 2014) (noting that the plaintiff had failed to provide evidence of the objective standard for commercially reasonable efforts in the FDA-regulatory context); *MBIA II*, 950 F. Supp. 2d at 617 (requiring evidence to define the "commercially reasonable" standard for a particular industry). A court will not engage in a hindsight comparison of the breaching party's actual conduct to that which could have been undertaken to produce a better result; a court should evaluate only whether the party's actual conduct was sufficient. *Holland Loader*, 313 F. Supp. 3d at 472–73 (citing *Bear, Stearns Funding, Inc. v. Interface Grp.–Nevada, Inc.*, 2007 WL 1988150, at *22 (S.D.N.Y. July 10, 2007)). At a minimum, however, "compliance with a 'commercially reasonable efforts' clause requires at the very least some conscious exertion to accomplish the agreed goal . . . ." *Holland Loader*, 313 F. Supp. 3d at 473.

3. Plaintiffs Have Not Shown that Sun Failed to Act in a Commercially Reasonable Manner

Because the EPA does not define "commercially reasonable efforts," it fell upon Plaintiffs to establish the objective standard by which Defendant's efforts should be judged. Plaintiffs declined to present an expert to establish an objective standard. Rather, Plaintiffs argue that Sun failed to engage in any conduct, and, therefore, did not act in a commercially reasonable manner. Specifically, Plaintiffs argue that, because Sun made no effort to reinstate development of the Tetrofosmin Products following Plaintiffs' request in 2015, Sun's conduct fails to meet the bare minimum required for commercial reasonability.

Plaintiffs argument, however, asks this Court to look only at Sun's actions after Alto requested that Sun allow Pharmalucence to resume development of the Tetrofosmin Products. This is too narrow a view. To consider Sun's actions, the Court must consider them in context, including the initial development work on the Tetrofosmin Products. Indeed, the question is not whether Sun took any action in 2015, but whether it was commercially reasonable, given prior efforts, for Sun to decline to restart development of the Tetrofosmin Products.

To assist in reviewing the efforts to develop tetrofosmin, Defendant put forth the testimony of Dr. Mark Robbins, who opined on typical considerations for selecting products for development in the Pharmaceutical industry. These considerations include the following: the overall commercial opportunity to assess the potential return on investment; the opportunity costs associated with the development of a particular product; the strategic fit with the company; the risks associated with development, including the overall difficulty of the project and the likelihood for success; the technology fit with facilities, equipment, and expertise of the development staff; the cost of development, including the required capital investment; and Intellectual property considerations. Judged against these objective standards, it was not commercially unreasonable to decline to restart development of the Tetrofosmin Products.

The overall commercial opportunity for the Tetrofosmin products was an increase in revenue between two and seven million dollars per year. However, as Alto wrote in September 2014, the Tetrofosmin Products faced significant headwinds from commoditization and low price point.

On the other side of the equation, Pharmalucence's initial efforts to develop the Tetrofosmin Products ran into difficulties with securing sufficiently pure API. Pharmalucence attempted, unsuccessfully, to secure an adequate supply of Tetrofosmin from June 2013 through October 2014. By September 2014, Alto was pushing Sun to abandon the Tetrofosmin Products and substitute a different product, Ultratag. By October 2014, Pharmalucence lacked the API

necessary to conduct further development experiments. Rather than continue this effort, Alto declined an offer from Dalton to attempt a custom synthesis of tetrofosmin API for just $5,000 and canceled the project. As of the time of Plaintiffs' request to resume development in 2015, none of this had changed. And Plaintiffs failed to offer any evidence that a supply of tetrofosmin API was available. While, in hindsight, Sun could have run down every lead—purchasing a batch of Tetrofosmin API from every supplier who offered to make one—the risk that the project would again stall for lack of materials remained very high.

Similarly, during the initial development phase, Pharmalucence discovered that tetrofosmin API would rapidly degrade in the presence of oxygen. While a short exposure would not cause significant degradation—approximately 2% at 30 minutes—exposure for around an hour would lead to at least 5% degradation. This was not an acceptable result as the required purity level of the tetrofosmin API was between 98% and 102%. In an ideal world, the exposure time on the Bosch Line could theoretically be as low as eight minutes. However, in practice, vials could sit on the line for around an hour. The Bosch Line at the Billerica Facility could mitigate exposure to oxygen but could not eliminate it. And Pharmalucence ran out of acceptable tetrofosmin API before it could conduct tests to determine what effect the oxygen-mitigation efforts would have on tetrofosmin API. If Sun proceeded with developing the Tetrofosmin Products, there was a very high likelihood that the mitigation efforts would not be sufficient to prevent degradation. If the mitigation efforts failed, then Sun would have to either modify or replace the Bosch Line to proceed with development and manufacture. Either option could be expensive, with a new fill line costing between $10 million and $ 20 million, and could require the Billerica Facility to cease manufacturing activities for three to five years while Pharmalucence installed a new fill line and secured FDA approval.

Finally, during the initial development efforts, Pharmalucence was working towards a co-development agreement with Cardinal that promised to defer some costs and guarantee a market for

the manufactured products. Such an agreement was no longer available in 2015, meaning the costs of development increased and the certainty of a market for the product decreased.

In the end, faced with higher costs, uncertain markets, uncertain supply, and risks of cost-prohibitive capital expenditures, Sun's efforts to develop the Tetrofosmin Products were commercially reasonable. Doing more would have subjected Sun's business to significant risk of loss to its commercial interests. These were products Plaintiffs sought to abandon and substitute prior to realizing that Sun would not designate substitute products. Plaintiffs' only interest in resuming development was for a chance to obtain the Milestone Payments. But Plaintiffs financial interest does not render an otherwise risky project commercially reasonable to pursue.

As a last-gasp argument, Plaintiffs claim that there is no evidence that it would not be commercially *unreasonable* to restart development of the Tetrofosmin Products. Despite the obvious burden-shifting issues raised by such an argument, the evidence at trial established that it would have been commercially unreasonable to restart tetrofosmin development. It was not be commercially reasonable for Sun to restart a project it had good reason to know would not succeed at the expense of other projects simply because Plaintiffs had a financial interest in the project.

F. Count VI: Breach of Implied Covenant of Good Faith and Fair Dealing

"The covenant of good faith and fair dealing embraces a pledge that neither party shall do anything which will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract." *Boart Longyear Ltd. v. All. Indus., Inc.*, 869 F. Supp. 2d 407, 419 (S.D.N.Y. 2012) (quotation marks omitted). This covenant "is implied in every contract governed under New York law." *Id.* "Accordingly, a breach of the implied duty of good faith is considered a breach of the underlying contract." *Id.* (citation omitted). "Even when a contract confers decision-making power on a single party, the resulting discretion is nevertheless subject to an obligation that it be exercised in good faith." *Travellers Int'l, A.G. v. Trans World Airlines*, 41 F.3d 1570, 1575 (2d Cir. 1994). However, "[t]he obligation of good faith and fair dealing does not negate a[n] expressly

bargained-for clause that allows a party to exercise its discretion, unless that clause imposes a limit on the discretion to be exercised or explicitly states that the duty of good faith and fair dealing applies." *O.F.I. Imps. Inc. v. Gen. Elec. Cap. Corp.*, 2017 WL 6734187, at *4 (S.D.N.Y. Dec. 29, 2017) (quotation marks omitted).

Plaintiff argues that Sun intentionally refused to recognize a substitute product or to reinstate tetrofosmin development in order to deny Plaintiffs' the Milestone Payments. First, as discussed above, the decision to refuse to reinstate tetrofosmin development was commercially reasonable and based on Sun's legal right to protect its commercial interest. As such, Plaintiffs have not proved that the decision was made in bad faith. Second, the Substitution Provision gives Sun sole discretion to substitute products. This provision contains no limitation or reference to the covenant of good faith and fair dealing. Therefore, the implied covenant does not limit Sun's discretion. *O.F.I. Imps. Inc.*, 2017 WL 6734187, at *4. That Sundaram at one point asked if Sun should substitute another product in place of the Tetrofosmin Products makes no difference. As written, Sun could exercise its discretion for any reason. While Sundaram considered a substitution of Ultratag at one point, the covenant of good faith and fair dealing does not morph his consideration into an obligation.

V. CONCLUSION

The Court has found that many of the positions taken by Plaintiffs in this case were not worthy of belief. Certain Plaintiffs—particularly Alto—made factual statements to the Court in this litigation that were contradicted by their own contemporaneous statements and the testimony of credible witnesses. As a result, the Court has found that they are not entitled to much of the relief that they sought in this case. At the end of the day, however, they are entitled to partial judgment in their favor with respect to the Last Man Standing provision because the plain text of the relevant agreement requires it.

The Clerk of Court is directed to enter judgment in favor of Plaintiffs as to Counts II and III and to enter judgement in favor of Defendant on Counts IV, V, and VI. The Clerk of Court is directed to enter judgment for Plaintiffs in the amount of $3,125,000, plus prejudgment interest calculated at 9% per annum[10] from March 21, 2019 through the date of judgment (Milestone four) and $3,125,000, plus prejudgment interest calculated at 9% per annum from July 12, 2019 through the date of judgment (Milestone six). Post-judgment interest shall accrue at the statutory rate pursuant to 28 U.S.C. § 1961 from the date judgment is entered until payment is made in full.

The Clerk of Court is directed to enter judgment as set forth above, terminate all pending motions, and close this case.

SO ORDERED.

Dated: October 13, 2021
New York, New York

GREGORY H. WOODS
United States District Judge

[10] Under N.Y. C.P.L.R. § 5004, the applicable interest rate for pre-judgment interest is nine percent per annum.